Title	Does Evidence-Based Medicine Serve Everyone? Representation, Reward and Risk In Phase I Clinical Trials
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Abstract

Evidence-based medicine is a vast industry created around supporting the testing of new therapies before they are prescribed in the general population. Previous researchers have been concerned with the representativeness of these trials, citing concerns of external validity for female patients and racial minorities. However, Phase I trials, where the therapy is tested on a small group of healthy volunteers, have not been studied as extensively. Recent work suggests this group of participants may be disproportionately Black and Hispanic in the United States, reflecting a phenomenon of serial participation. These participants are often unfairly disadvantaged in the labor market, often facing unemployment, and are attracted to Phase I participation for the payment. These findings have not been replicated with a systematic review, as the original researchers relied on self report data, recruiting at trial centers themselves. This methodology is prone to selection bias, as it relies on permission. The present study was a systematic review of publicly available Phase I trials with the goal of clarifying factors which affect female enrollment as well as determining if enrollment by race is affected by whether or not the participants receive therapeutic benefit. A total of 300 articles reporting on 384 trials were included in this analysis. I found overall low female enrollment, except for in trials which were conducted in more than one global region ($p < .001$). Pharmacokinetic studies, pharmacodynamic studies, and studies conducted in Africa were also less likely to enroll female participants ($p < .001$). Within the United States, Black and Hispanic participants were found to be overrepresented as compared to their share of the population according to Census data, however this was not predicted by whether or not they participated as healthy volunteers as opposed to patients ($p > .05$). Most of the trials in the sample were conducted on healthy volunteers, however (76%). Future researchers may consider investigating a larger sample of trials with participant benefit for a more fair comparison.

Introduction

The industry of evidence-based drug development begins in the laboratory, then eventually moves to human clinical trials (Umscheid et al., 2017). Clinical trials themselves have become an object of research, with much scholarship devoted to investigating the representativeness of participants in therapeutic trials (Fisher, 2011). Since regulatory bodies and clinicians rely on efficacy and safety information from these trials, systemic low enrollment of women and racial minorities is important to study (Liu & Dipietro-Mager, 2016). However, therapeutic trials involving patients are not the only types of trials. New therapies are tested on healthy volunteers in the early phases. Although scholarship on the representativeness of this group is rare, recent evidence suggests that racial minorities and people facing unemployment may be overrepresented as paid volunteers (Fisher, 2011). This is concerning, as there are already healthcare gaps between different races and social classes. In general, non-White people have less access to cutting edge treatments and medical care, especially if unemployed (NASEM, 2017). Risk is necessary for evidence-based medicine, as there will always be a group of individuals who are first to consume a new therapy. Yet, if those taking on this burden do not tend to have access to these therapies once they are on the market, this has implications for the research principle of justice. The present study contributes to a greater understanding of the dynamics of risk and benefit with a review of published Phase I clinical trials, examining participant characteristics and exploring influences on these trends.

Clinical research takes place over four phases. During Phase I trials, the therapy is administered to humans for the first time, and scientists determine the maximum tolerated dosage of the therapy and begin modeling a safety profile (Umscheid et al., 2017). Researchers tend to prefer enrolling healthy volunteers rather than patients with the target condition, to ensure any observed effects are from the intervention rather than a background health condition (Koonrungsesomboon et al., 2016; Dresser, 2009). These subjects are paid in order to compensate for the lack of therapeutic gain (Fisher et al., 2021; Koonrungsesomboon et al., 2016). Some Phase I trials enroll patients with the target condition, however. As an example, oncological therapies such as chemotherapy drugs and monoclonal antibodies present serious risks to healthy patients, in which case a patient population is more appropriate (Itahashi et al., 2019; Dresser, 2009). Later phases of clinical research (II through IV) are devoted to clarifying the safety and tolerability in different contexts and gleaning an idea of the therapeutic quality of the new therapy. As such, they nearly always recruit from the patient pool (Umscheid et al., 2017).

Concern over low female participation is one of the most prominent angles in the critical appraisal of the clinical trial process. Liu and Dipietro-Mager (2016) describe the historical precedent for this research trend, noting the tendency for early clinical trials to wholly exclude female participants. Trialists have always preferred a homogenous sample, in order to enhance the internal validity of their studies. Because the conduct of clinical research began and continues to be a male-dominated field, this homogenous population tended to be male. Female bodies were thought to have too much hormonal fluctuation to be reliable test subjects, yet physiologically similar enough that results could be generalized (Liu & Dipietro-Mager, 2016). This assumption has since been falsified. Male and female bodies have distinct underlying physiology, leading to differences in drug effects. The social component of gender also leads to differences in the way men and women interface in their environment (Liu & Dipietro-Mager, 2016).

Despite a push to recruit more female participants since the 1990s, evidence suggests persistent disparity in some cardiovascular disease foci (Carcel et al., 2021; Gong et al., 2019; Jin et al., 2020; Scott et al., 2018; Tahhan et al., 2020; Khan et al., 2020). The pattern is less clear in other disease groups, with some studies finding adequate or even overrepresentation when adjusting expectations based on their share of the disease burden, and others finding systemic low

enrollment (Chen et al., 2018; Downing et al., 2016; Eshera et al., 2015; Geller et al., 2018; Palmowski et al., 2019). Nevertheless, any lasting disparity in participation has had consequences. Female patients are more likely to be hospitalized for severe adverse drug reactions (Davies & O'Mahoney, 2015; Zopf et al., 2008; Pirmohamed et al., 2004; Yu et al., 2016). Additionally, Liu and Dipietro-Mager (2016) examined the rationale provided by regulatory agencies when removing prescription drugs from the market, finding that most were recalled due to increased risk for women. If women were included in greater numbers in early clinical trials, differences in pathophysiology could be taken into account earlier on in the process, leading to more accurate dosing and safety information (Bale & Epperson, 2017; Franconi & Campesi, 2014).

Scholars are also interested in the enrollment of racial minorities. This body of research is mostly localized to the United States (USA) and focuses on Black participants in therapeutic trials (Fisher, 2011). This is likely because reporting race or ethnicity is relatively uncommon outside the USA (Starks et al., 2019; Charrow et al., 2017; Cwalina et al., 2017; Corbie-Smith et al., 2003). There is also nuance lost to the concepts of race and ethnicity. They are distinct constructs, but are mostly used interchangeably (Bokor-Billmann, et al, 2020). Race is defined as the socially constructed identity formed around the shared physical characteristics of people from similar ancestral backgrounds. Ethnicity is also a social identity, created around shared cultural practices and language (Mersha & Abebe, 2015). In clinical research, differentiating between these terms is rare, leading to confusion. In their review of 995 clinical trials, Bokor-Billmann and colleagues (2020) found 81 different race or ethnicity classification systems. This is expected, as ethnicity classifications vary globally (Mersha & Abebe, 2015).

Despite these inconsistencies, there is a relatively robust finding that White patients are most likely to participate in therapeutic clinical research, with other races systematically underrepresented when compared to their share of the disease burden. This pattern has been observed for multiple distinct disease states in the USA (Strait et al., 2019; McGarry & McColley, 2016; Cwalina et al., 2021; Robbins & Bernat, 2017; Polo et al., 2019). Medical mistrust may play a role in this discrepancy, as the USA has a recent history of unethical medical experimentation on Black patients (Clark et al., 2019; Scharff et al., 2010). Another explanatory factor is relative resource deprivation. Black and brown communities in the USA are less likely to have reliable healthcare infrastructure (Khullar, 2018). This could reduce the likelihood that these patients would have access to a clinical trial center, or that their physicians would be aware of these opportunities.

The reviews cited thus far cannot answer the question of enrollment demographics in Phase I clinical research, as they were concerned with external validity and focused on therapeutic trials. Fisher (2011) posits that this focus obscures important aspects of healthcare inequality, as Phase I participants are already likely to be a member of a vulnerable group. In the USA, there appears to be a phenomenon of serial participation among participants facing unemployment, attracted to the payment (Kalbaugh et al., 2021). Paid clinical labor can be characterized as inherently exploitative, given the risk involved in participation. Although severe side effects are rare, less serious adverse events such as headaches, nausea, drowsiness, and dizziness are common (Kerbrat et al., 2016; Emanuel et al., 2015). In addition, participants must undergo numerous diagnostic tests such as blood draws and X-rays. These procedures have a much smaller potential risk, however this can be compounded since participants are often asked to repeatedly endure them (Owonikoko, 2013). Fisher (2015) points out that, should there be more serious or long term side effects, the groups of people who are most likely to enroll are also unlikely to have the resources or time to pursue litigation.

Research on Phase I volunteer is scarce. One consistent finding across multiple methodologies is that female participants comprise only about a quarter of Phase I participants (Labots et al., 2018; Liu & Dipietro-Mager; Kalbaugh et al., 2021). According to a recent study from

Kalbaugh and colleagues (2021) where Phase I trial participants were administered surveys at trial centers, Black and Hispanic participants appear to be overrepresented, comprising an estimated two-thirds of Phase I participants. Emanuel and colleagues (2015) performed a large review of individual-level Phase I participant data from Pfizer and also found overrepresentation of Black participants, but did not comment on this finding in their paper. Kalbaugh, Fisher and their associates are among the only researchers studying the motivations of these volunteers, including those who repeatedly enroll. These volunteers report traveling large distances and significantly altering their lifestyles in order to meet eligibility requirements (Monahan & Fisher, 2015). In their qualitative study on volunteer motivations, Fisher and colleagues (2021) found that many of these participants report clinical trial participation stipends as their primary source of income. Kalbaugh and colleagues (2021) report on the economic precarity some of these participants face, arguing that recruitment is, to some extent, dependent on social disadvantage, with one interviewee pointing out that serial participants often take on the risk because they "have nothing to lose" (Kalbaugh et al., 2021).

Those who participate in Phase I clinical trials as patients with the target condition appear to be more privileged, with 90.0% self-identifying as White and over half holding private health insurance. Less than 4% were fully uninsured (Seidenfeld et al., 2008). These results, in combination with research on later phase therapeutic trials summarized above, suggest that when there is therapeutic benefit involved, White patients tend to be overrepresented, while racial minorities are underrepresented. Clark and colleagues (2019) find that a lack of awareness of clinical trial opportunities, as well as lack of the resources to take advantage of these opportunities, are a key barrier to racial minorities' participation in therapeutic clinical trials. This could be related to underlying health disparity, as racial minorities in the USA tend to receive poorer medical care, thus it is possible that their physicians are less likely to be aware of clinical trial opportunities their patients could participate in (NASEM, 2017). Paid healthy volunteers who belong to a racial minority group are also disadvantaged, however, rather than being therapeutic, their participation is to serve their financial interests (Kalbaugh et al., 2021).

Although previous work has investigated the characteristics of Phase I trial participants, it has mainly been conducted prospectively, at Phase I recruitment centers. Given that they have to have permission from the institution, and some facilities decline access, this can lead to potential biases (Fisher, 2015). A review of published clinical trials, on the other hand, provides access to information about participants without relying on an invitation from a trial center, while also providing data about the clinical characteristics of the trial. In the present review, a novel mixed methods approach was adapted, using qualitative methods to examine rationale for the exclusion of female participants, as well as multivariate analysis to clarify influences on participant characteristics, similar to the research summarized above. To the best of my knowledge, no previous review has attempted to compare participation of different groups based on whether the participant is receiving therapeutic benefit. Additionally, there is little research on Phase I trial participants outside the USA.

Research Questions and Theoretical Approach

1. What are the characteristics of individuals who participate in non-oncological Phase 1 clinical trials?
2. How do these characteristics differ between trials on healthy volunteers versus patients of a condition, and what motivates these differences?
3. What reasons, if any, are provided for the exclusion of female participants in clinical trials?
4. If there is systematic low enrollment for female participants, what factors motivate these?

In the USA, Black and Hispanic people are likely to face discrimination during hiring (Quillian & Midtboen, 2021). In addition, Black people specifically face disproportionate incarceration rates (Wildeman & Wang, 2017). This means Black men are more likely to be felons, which means they may experience difficulties in finding employment in some states where it is legal to consider applicants' criminal records in hiring decisions. Kalbaugh and colleagues (2021) find that repeat participants treat clinical trial involvement as though it were a full-time job. Fisher (2015) found a certain "banalization of risk" amongst participants, noting that their main fear with participation was that they would not be selected for the next study, and not the bodily risk. Although participating can help some of these participants earn an income while searching for more stable employment, it is social inequality which fuels this phenomenon in the first place. It is likely that these individuals would not be seeking out work which puts their body at risk if they had fewer barriers to traditional employment in the labor market. I hypothesize that Black and Hispanic participants will then be more likely to participate in Phase I trials, but only in studies with no therapeutic benefit, and only in the USA. For trials enrolling patients with the indication who may benefit therapeutically, I predict underrepresentation of Black and Hispanic participants.

Clinical trial participation is not as lucrative of an option for women as it is for men. Many Phase I studies require female participants to be post-menopausal or surgically sterile (Liu & Dipietro-Mager, 2016). In addition, women have other options, such as becoming a surrogate mother. This, combined with the tendency for Phase I trials to exclude female participants, means there will likely be lower enrollment for women. Other than this, no formal hypothesis was constructed for female enrollment.

Methods

Systematic Search

Eligible Phase I clinical trials were sourced with an advanced search on PubMed, selected due to its dominance in health sciences (White, 2020). I searched 'clinical trial,' 'randomized controlled trial,' 'controlled trial,' and 'RCT,' separated by Boolean operator 'OR.' From these results, I filtered for only English-language articles reporting on a human Phase I trial, published in 2019. The year 2019 was selected in order to glean an accurate and unbiased view of Phase I trial participation under normal circumstances without including studies which were either related to the COVID-19 pandemic, or affected by it.

Eligibility Criteria. The articles selected for this review report on at least one Phase I trial testing some aspect of an investigational compound by administering it to either human volunteers, or human patients with the indicated condition.

Exclusion Criteria. The present study focuses on molecular entities, or drugs. The validation of surgical procedures, cell therapies, durable medical equipment, and diagnostic techniques can also involve Phase I clinical trials, however these are designed differently and tend to include only patients with the target condition. These types of studies were excluded in order to ensure the design components of each trial were as similar as possible. Similarly, studies trialing oncological therapies were also omitted, as these can be expected to mainly recruit patients with various cancers. Studies reporting on an analysis of previous clinical trial data which was published

elsewhere were also not eligible for this review, as these trials tend not to go into detail about the methodology employed by the original investigators.

Identification of Eligible Clinical Trials. The above search was performed on 03 January, 2022, and returned 1,480 results, which were uploaded to Rayyan in BibTeX format. Ten duplicate articles were deleted. The titles, abstracts, and metadata of the remaining articles were reviewed for eligibility determination on Rayyan. Of these, 147 articles required full text review in order to determine eligibility. Reasons for ineligibility are summarized in Table 1. A total of 469 articles remained eligible for inclusion.

Table 1: Reasons for excluding articles from the present review.

Exclusion Reason	No. studies
Cancer therapy	824
Non-pharmacological intervention	117
Post-hoc analysis	49
Not a human clinical trial	20
Interim analysis	5
Unable to determine methodology	3
Retracted article	1
Full text not available through any known means	1

Randomization. Due to this high volume, 300 articles were randomly selected for review from this pool. Each eligible article was assigned a number in sequential order while alphabetized by the first author's last name. Using the `random.sample()` Python command, I produced 300 random, non-repeating integers between 1 and 469. See Python Software Foundation (2022a) for details on this method of randomization (the random.sample section). I used `sort()` to sort this list sequentially, and only extracted data from the articles corresponding to the numbers listed in the output (See Python Software Foundation, 2022b, under Lists, then sort).

Coding and Data Synthesis

The full text of each of the 300 studies was reviewed. If any information could not be obtained with full text review, I reviewed supplemental materials and registries. Coding rules were determined based on a review of 20 randomly selected studies. These studies were reviewed and coded for metadata, information about the therapy and disease state, trial purpose, design, participant screening criteria, participant characteristics, and some trial procedures. For detailed information on definitions and coding criteria, see the codebook, included in Appendix A. Additionally, see Appendix B for more information on how indication, disease classification, and sex-specificity was determined. The full dataset has also been included in Appendix D.

Data Analysis

Frequencies for location, indications, design components, and study procedures were calculated. For each trial, and for sex, race, and ethnicty, the sum of participants in each category was calculated, then subtracted from the sample size in order to determine the number of participants with unknown sex, race, or ethnicity. Trends in enrollment by sex, race, and ethnicity were calculated as mean and median enrollment per trial, as well as a proportion of the total number of participants with known sex, race, or ethnicity information. These trends were calculated for all trials, for each global region, for non-US studies, for only US studies, and for each region within the US. A qualitative analysis on the rationales provided for the exclusion of participants by sex and race was also planned. For female enrollment, no formal hypothesis was made except that it would be lower than male enrollment. Therefore the first step was to examine cross tables for various factors to determine which may influence enrollment. Because race and ethnicity proportions were expected to differ between global regions, analyses on factors influencing these numbers were limited to only trials in the USA. Linear regression analyses were planned with these trials in order to determine the independent effects of US region, therapeutic benefit, and first-in-human status on mean per-trial enrollment proportions for White, Black and Hispanic participants. All analyses were performed with Microsoft Excel or SPSS. Syntax has been included in Appendix E.

Ethical Considerations

The protocol for this research project was submitted to the Ethics Committee at Utrecht University and was approved and filed under 22-0671.

Results

Article and Trial Characteristics

A total of 384 eligible Phase I clinical trials were reported in the 300 articles. All five global regions were represented in the sample of trials, however the majority were performed in the Americas, Europe, or Asia. See Table 2 for enrollment trends by global region. See Appendix Table 1 for a list of countries in the sample of trials and how many trials were conducted there.

Table 2: Summary of trials and participants included in all five global regions.

Characteristic	All	Africa	Americas	Asia	Europe	Oceania	Multiple
Trials, total	384	13	160	61	98	18	19
Participants, total	18,636	1,403	7,497	3,079	4,338	970	1,349
% (of total)	100%	7.50%	40.20%	16.50%	23.30%	5.20%	7.20%

n (median)	32	40	31	32	34	25	24

Disease groups were diverse in the sampled trials. Few indications were deemed sex-specific. Four trials studied male-specific indications, summarized in Appendix Table 4, and 11 studied female-specific indications, summarized in Appendix Table 3. See Appendix Tables 5, 6, 7 and 10 for an overview on the therapies included, trial purposes, designs, and procedures, respectively.

Participant Social Characteristics

Reporting of Characteristics. The vast majority of trials reported proportions by sex (85%), and most reported at least some of their racial demographics (73.2%), however few articles reported any ethnicity information (26%). About one-quarter of the trials reported on sex, race, and ethnicity in some way (100 trials; 26%). Partial demographic reporting was also common, with slightly more than half reporting only sex and race (207 trials; 54%), 14% reporting only sex proportions (14%), and four trials reporting only race proportions (1%). No trials reported only enrollment by ethnicity without race and sex proportions, and no trials reported ethnicity and sex without race as well. A total of 14 trials (3.6%) did not report any demographic characteristics at all, either in the text, the supplemental materials, or ClinicalTrials.gov. No studies reported on sex or gender minorities nor distinguished between the sex and gender of their participants in any way.

Participation by Sex. The studies included in the sample included a total of 18,636 participants. Of those, 11,227 were male, 6,576 were female, and for 833 participants, the sex could not be determined. Female participants comprise 36.9% of total participants with known sex. Slightly more than half of the trials recruited a sample with less than 40.0% female enrollment (200 trials; 52%), while only 28% recruited a sample between 40.0% and 60.0% female (109 trials). Few trials enrolled female participants as more than three-quarters of their sample (45 trials; 11.7%). Female enrollment varied by global region as well, with African studies enrolling a mean proportion of female participants of 22%, despite higher overall enrollment. Female enrollment by global region is summarized in Table 3. First-in-human, safety, pharmacokinetic, and pharmacodynamic studies all excluded female participants more than 10% of the time, and also had lower mean and median enrollment, with pharmacokinetic studies including no female participants the most often, 18.7% of the time. By contrast, studies with therapeutic benefit for participation, efficacy studies (a category which includes all therapeutic benefit studies), and bioequivalence studies rarely excluded female participants. Detailed trends in female enrollment for each trial purpose is summarized in Table 4.

Table 3: Trends in female enrollment across global regions.

	All*	**Multiple**	**Africa**	**America**	**Asia**	**Europe**	**Oceania**
Participants, total	17874	559	1431	7497	3079	4338	970

Female, % of total participants	35.2%	43.5%	40.5%	38.8%	32.3%	31.7%	19.0%
Female, mean % per trial	32.9%	45.7%	22.7%	35.3%	30.4%	29.4%	32.4%
Female, median % per trial	33.3%	50.0%	20.8%	33.3%	33.3%	30.6%	38.0%
No. of trials excluding female participants	76	0	6	19	17	33	1

*This measurement only includes trials with known global region.

Table 4: Female enrollment for each trial design.

	Trials (% of total)	Trials excluding females (%)	Female enrollment, mean per trial	Female enrollment, median per trial
Safety, tolerability, or TQT studies	87.0%	17.7%	18.3	10
Pharmacokinetic studies	75.0%	18.2%	12.7	7
Pharmacodynamics or bioavailability studies	35.7%	11.2%	12.8	6
Bioequivalence studies	6.0%	0.8%	25.4	8
Efficacy studies	27.9%	2.3%	34.2	14
First-in-human studies	64.1%	13.3%	15.8	8
Therapeutic benefit studies	21.6%	2.1%	18.9	9

Multiple linear regression was performed to determine if global region, treatment benefit, first-in-human status, or endpoints of pharmacokinetics, pharmacodynamics, bioequivalence, or efficacy were significantly predictive of female enrollment. Safety was not included in this model, as the vast majority of studies in the sample measured some component of safety. Pharmacokinetic and/or pharmacodynamic studies had statistically significant lower mean female enrollment, as did studies conducted in Africa or multiple regions ($R^2 = 0.117$, $F(11, 340) = 4.082$, p

< .001). No other correlations were statistically significant. The model is summarized in Table 5, with significant results in bold.

Table 5: Regression results for female enrollment as predicted by various design components.

Variable	Unstandardized B	Coefficients std. error	Standardized Coefficients Beta	t	Sig.
Non-pharmacokinetic studies	.088	.042	.136	2.100	**.037**
Treatment benefit studies	-.022	.039	-.033	-.576	.565
Non-first-in-human studies	.044	.031	.075	1.396	.164
Non-safety, tolerability, or TQT studies	.035	.044	.042	.791	.429
Non-pharmacodynamics or bioavailability studies	.078	.033	.133	2.385	**.018**
Non-efficacy studies	-.072	.040	-.115	-1.777	.076
Multiple global regions	.182	.071	.144	2.556	**.011**
Africa	-.207	.080	-.137	-2.579	**.010**
Asia	-.071	.041	-.095	-1.727	.085
Europe	-.052	.036	-.081	-1.446	.149
Oceania	-.022	.069	-.017	-.326	.744

Participation by Race/Ethnicity. Enrollment by race and ethnicity between global regions is summarized in Appendix Tables 9 and 10. Within the USA, White participants comprised 61.3% of total participants with known race, while they make up about three-quarters of the population of the USA, according to the U.S. Census Bureau (2020). Black participants comprised 39.5%, while they make up only 13.4% of the USA population. Asians were slightly underrepresented at 4% of total participants in the trials, but 5.9% of the population. Native American and Pacific Islanders make up 0.2% of the population both according to the Census and in the trials. Middle Eastern participants were not included in this analysis, as no trial in the USA reported their inclusion. Hispanic and Latino participants comprised 27.9% of participants with known ethnicity, and they comprise 18.5% of the population (U.S. Census Bureau, 2020). Note however that the ethnicity could not be determined for more than half the participants in the included trials. See Tables 6 and 7 for enrollment as a percentage of participants whose race and/or ethnicity is known compared to population data.

Enrollment by race and ethnicity also varied between regions. In the Northeast, Black participants were the majority, despite comprising only 11.9% of the population in that region, according to the Census (2020). White participants were the majority in all other regions, however Black participants were overrepresented according to their share of the population in all other regions as well. Black Americans are 10.4% of the population in the Midwest, but were 39.% of participants in these trials. In the South, 19.3% of the population is Black, while 27.1% of the participants in these trials were. In the West, they are 4.6% of the population, but were 13.6% of trial participants. Asian enrollment was higher in Western trials, however almost half the subjects participating in the 14 Western studies did not have known race. Native American and Pacific Islander enrollment was below 1% in all US regions.

Hispanic enrollment also varied in different regions, with higher enrollment in the South and the West. In the South, Hispanic participants comprise 19.3% of the population but were 48.1% of trial participants for those which reported ethnicity. In the West, 29.1% of the population is Hispanic, while over half of these trial participants were (U.S. Census Bureau, 2020). Note, however, that ethnicity could not be determined for almost half of the subjects who participated in this region. See Tables 6 and 7 for more detailed information on these trends.

Table 6: Summary of enrollment for each race by US region in comparison to US Census data.

Characteristic	**All US**	**NE US**	**MW US**	**S US**	**W US**	**US Census***
Known Race, total	5471	824	982	1045	339	331,449,281
White, % of total	61.3%	33.5%	58.4%	69.8%	62.5%	76.30%
Black, % of total	33.0%	60.8%	39.5%	27.1%	13.6%	13.40%
Asian, % of total	4.0%	4.4%	0.7%	1.6%	22.7%	5.90%
Native American, % of total	0.5%	0.4%	0.5%	0.2%	0.3%	1.30%
Pacific Islander, % of total	0.2%	0.1%	0.0%	0.2%	0.0%	0.20%
Multiracial, % of total	1.1%	0.8%	0.9%	1.1%	0.9%	2.80%

*Data were pulled from the U.S. Census Bureau Quick Facts page (U.S. Census Bureau, 2020).

Table 7: Summary of enrollment for each ethnicity by US region in comparison to US Census data.

Characteristic	**All US**	**NE US**	**MW US**	**S US**	**W US**	**US Census***
Known Ethnicity, total	3106	386	426	520	267	331,449,281

Hispanic, % of total	27.9%	17.9%	8.7%	48.1%	56.2%	18.50%
Not Hispanic, % of total	72.1%	82.1%	91.3%	51.9%	43.8%	60.10%

*Data were pulled from the U.S. Census Bureau Quick Facts page (U.S. Census Bureau, 2020).

The distribution of trials with a benefit to participation was not even across regions. In the West, there were no trials with a therapeutic benefit, and very few were conducted in the Midwest and the South, with the most in the Northeast region, at 10 trials with therapeutic benefit. Additionally, there were 40 trials conducted in multiple regions with aggregated demographics reported, and/or the region was not available. See Appendix Table 11 for a summary of how many trials with or without therapeutic benefit were conducted in each region in the USA.

A linear regression analysis was performed on only US-based studies to test if the presence of therapeutic benefit or US region were predictive of Black enrollment. The model was statistically significant, however only for US region. Black participants were less likely to participate in the Midwest, South, or West ($R^2 = .489$, $F(4, 78) = 6.113$, $p < .001$). No effect was observed for treatment benefit ($p = .592$). An additional *ad hoc* split sample linear regression analysis was performed on only Northeast studies to determine any effects of treatment benefit, as this was the only region with majority Black participants, and was the only region with heterogeneity in whether or not there was therapeutic benefit to participation. Therapeutic benefit was not related to enrollment in this region in this model either ($p = .240$). The results of both analyses are presented in Tables 8 and 9, respectively.

Table 8: Regression results for Black enrollment by US region and treatment benefit.

Variable	**Unstandardized B**	**Coefficients std. error**	**Standardized Coefficients Beta**	**t**	**Sig.**
Midwest	-.153	.066	-.281	-2.325	.023
South	-.180	.067	-.316	-2.696	.009
West	-.369	.085	-.486	-4.343	<.001
Therapeutic Benefit	.048	.089	.057	.538	.592

Table 9: Regression results for Black enrollment in the Northeastern USA and treatment benefit.

Variable	Unstandardized B	Coefficients std. error	Standardized Coefficients Beta	t	Sig.
Treatment Benefit	-8.810	7.326	-.230	-1.203	.240

Another, similar regression analysis was performed to determine if Hispanic enrollment was affected by region and treatment benefit. For this model, too, region was a predictor of Hispanic enrollment but not treatment benefit, where Southern and Western trials had higher mean Hispanic enrollment (R^2 = .608, F(4, 43) = 6.292, p < .001). This model is summarized in Table 10. It was not possible to perform an additional analysis on only Southern and Western trials, because there was only one trial in that sample which had therapeutic benefit for participation.

Table 10: Regression results for Hispanic enrollment in the USA and treatment benefit and region as predictors.

Variable	Unstandardized B	Coefficients std. error	Standardized Coefficients Beta	t	Sig.
Treatment Benefit	-0.049	0.117	-0.057	-0.421	0.676
Midwest	-0.109	0.09	-0.179	-1.205	0.235
South	0.265	0.09	0.436	2.939	0.005
West	0.262	0.105	0.352	2.496	0.016

One final linear regression analysis was performed for White enrollment as it is predicted by whether or not participation in the study would lead to therapeutic benefit. No effect was found (R^2 = .070, F(1,123) = 0.598, p = .441). This model is summarized in Table 11.

Table 11: Regression results for White enrollment in the USA and treatment benefit.

Variable	Unstandardized B	Coefficients std. error	Standardized Coefficients Beta	t	Sig.
Treatment Benefit	.047	.061	0.07	0.774	0.441

Exclusion by Sex. Most studies did not exclude anyone based on sex (70.1%). However, 60 studies excluded all female participants (15.9%) and another 33 (7.8%) excluded women of childbearing potential (requiring female participants to be surgically sterile and/or post-menopausal). Most (43 out of 60) of the studies which excluded female participants did not explain why and were not male-specific conditions. Three of these trials were for male-specific conditions, however none of these explicitly stated this was the reason for the exclusion (702580, 703560, 703950). None of the 33 trials which excluded female participants of childbearing potential provided a rationale for this, and none were male-specific conditions. The authors of one such study stated that the indication occurs more often in female patients, yet still excluded the majority of female patients in their screening criteria (698920). Of the 11 trials which were not male-specific indications and provided a rationale for excluding women, six cited concerns of affecting a future, hypothetical pregnancy, although three of these were from the same article. Two studies which involved

frequent urine collection cited urethral differences in the sexes, one of which had a target condition with a higher prevalence in female patients (690600). One study which excluded female participants stated that "no clinically meaningful sex difference was determined by [previously published] population pharmacokinetic modeling" (700490). One trial stated that the prevalence of the indication is higher in male patients (690400). The last trial specified that their selection criteria excluded female participants in order to achieve homogeneity in their sample (694233).

Very few studies limited male participation in any fashion, with 18 trials excluding all male participants (4.7%) and three only recruiting surgically sterile male participants (0.8%). None of the studies requiring male participants to be surgically sterile provided a rationale for this screening criteria, however all of the trials which excluded male participants were either female-specific (five trials), or gave an explicit reason for their exclusion (13 trials). Three trials excluded male participants because the trial was testing a new therapy on a population that is female-specific, even though the target condition was not necessarily (e.g., lactating mothers and birth control users). There were three studies with a non female-specific condition but the target patient population was female (e.g., a vaginally administered therapy). Two studies stated that the indication was more common in female participants. One article reported on five clinical trials for a therapy treating a female-specific infection but provided an additional rationale that preclinical animal testing in male subjects revealed toxic effects to male gonads (695361, 695362, 695363, 695364, 695365).

Discussion

The present study was conducted to explore enrollment in Phase I trials for female participants and each race and ethnicity, as this phase of the clinical trial process is relatively underrepresented in critical appraisal research. The primary finding was that Black and Hispanic participants are overrepresented in Phase I trials in the USA as a whole, and in all regions, while White participation was lower than what would be expected. However neither White, Black, nor Hispanic enrollment were predicted by whether or not the therapy provided a benefit for participants. This finding replicates Kalbaugh and Fisher's (2021) work, but also raises questions about what is accounting for this overrepresentation. Notably, the majority of US-based studies in the sample were conducted on volunteers, which was a limitation incurred by the relatively small sample size in this study. Most US regions had fewer than 10 trials with therapeutic benefit, making it more difficult to determine patterns based on region. Future researchers should consider including a larger sample with only the USA, which would include more studies from each region.

The finding of low female enrollment was expected, replicating prior findings that female participants are underrepresented in Phase I clinical research (Liu % Dipietro-Mager, 2016). The novel qualitative analysis of rationales provided for the exclusion of participants by sex reveals that male bodies are still considered to be the default research subjects. Excluding male participants appears to require justification, given that all studies which excluded male participants either gave a reason for doing so, or were studying a female-specific therapy. By contrast, the exclusion of female subjects was seldom explained. For studies which did explain, reproductive concern was commonly cited, however no authors provided a rationale or previous research for why reproductive mechanisms would be harmed in the first place. By contrast, the only study which excluded male participants out of reproductive concern explained that preclinical findings in male animals showed fertility damage. Additionally, some studies which excluded female participants simply stated that the reason for excluding them was simply that male participants could adequately answer their research question, further reinforcing the idea of male defaultness.

The finding that pharmacokinetic studies were both more likely to exclude female participants, and were predictive of low mean enrollment is alarming. These early pharmacokinetic and pharmacodynamic studies are crucial in establishing a safety profile for the new therapy, and are used to inform labeling and dosing decisions. These studies track the therapy as it moves through the body (Eason, Bonner & Parke, 1990). Liu and Dipietro-Mager (2016) found that female patients are overrepresented in hospital admissions for drug overdoses. It is possible that their relative absence in pharmacokinetic studies accounts for this finding. Additionally, historical biases in viewing the female body as primarily a reproductive one could be at play. If male bodies are seen as the default, and female bodies are reproductive bodies, then male bodies should be used to study the effects of new therapies, but female bodies should not be placed at risk, since it may harm their reproductive potential.

Statistically significant low mean female enrollment in African studies was surprising, as total female enrollment in Africa was higher than all other global regions. The exception to this was for multi-region studies. These trials had representative female enrollment according to all metrics, and none excluded female participants. Because this is not a "location" per se, it is difficult to reach any conclusions on this finding. There may be a country or a region which is underrepresented as the sole location for data collection, but is still hidden in this category which accounts for this difference. Notably, only 13 studies in the sample were conducted in Africa, and only 19 were conducted in multiple regions. Researchers interested in clarifying female enrollment in Phase I trials across global regions could consider another, larger review over a longer period of time.

As far as I know, this was the first review to investigate enrollment by US region, and the first to disaggregate enrollment characteristics based on the type of participant. It is also the first to perform the analysis from the standpoint of ethical rather than medical concerns. This framing allowed a more complex, multivariable analysis to investigate the factors which may lead to overrepresentation. Other study designs intended to investigate Phase I enrollment require permission from participants and institutions, and this can bias who is included in the analyses. A review of publicly available published trials removes this bias. This review also was the first in this field to employ a mixed methods analysis with both quantitative and qualitative analysis, and to collect data on a large number of variables. The dataset could prove to be a valuable resource for future researchers, as it represents a birds' eye view into Phase I non-oncological research in general, with a diverse array of trial purposes, designs, therapies, and conditions.

This chosen design was not without risk of bias, both in study selection and coding. Only one researcher performed the systematic search and coding process. In addition, the dataset is limited to only Phase I trials which were published and posted to PubMed. Although this resulted in a diverse cross section of clinical trials which may not have been the case with other methodologies, there may still be features that published trials have and others do not. Boggert (2017) found that publication was uncommon in Phase I trials, for instance, but was unable to determine which factors influence publication. Future researchers may consider only reviewing trials which led to an approval. Another potential methodology could be to request data directly from pharmaceutical companies.

Aside from the low number of studies with therapeutic benefit, another limitation was the conception of "sex-specific" as two binary variables reliant on only the ICD-10-CM guidebook. Although this approach allows expedient coding, a literature review may provide a more accurate and nuanced picture of prevalence by sex. Some conditions are merely more common in one sex over the other, but are not considered "sex-specific." As an example, urinary tract infections can occur in any sex, however female patients are about 30 times more likely to have them due to differences in urethral physiology between the sexes (Harrington & Hooton, 2000). It may then be reasonable to exclude all male participants from trials related to this indication, although it is not

considered female-specific. On the other hand, it may be important to include rare subgroups in clinical research. For future researchers, it may instead be fruitful to consider the target patient population instead of only the indication.

The present study was the first systematic review to attempt to replicate preliminary findings about the characteristics of Phase I volunteers. Black and Hispanic participants were not found to be overrepresented as healthy volunteers in Phase I trials, however they were overrepresented in Phase I trials as a whole. Additionally, this review sheds light on some dimensions of female participation in clinical research, mainly that their exclusion is not often rationalized or explained. In addition, pharmacokinetic and pharmacodynamic studies are less likely to recruit female participants. While limited by a small number of studies and limitations imposed by the use of review as a methodology, this study provides a birds' eye view into Phase I clinical trial enrollment demographics, and some potential influences on this phenomenon.

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Appendix B. Coding of Indication

Indication. First, the target condition was coded using ICD-10-CM, a series of internationally standardized alpha-numeric sequences which correspond to medical conditions and symptoms (World Health Organization, 2011). As no study authors specified ICD-10 codes in their manuscripts, these were sourced by searching the name of the condition on ICD-10 Data (https://www.icd10data.com/), a free web source for coding. When multiple codes applied and no specific code matched the description of the condition as provided by the study authors, the most general code was selected (e.g., J45.90, or 'asthma, unspecified').

Classification. An additional variable was included for the disease classification. Although this variable is not expected to necessarily affect enrollment proportions for any group, it was coded for as an exploratory variable, as well as to determine whether the condition was sex-specific (see below). The 20 levels for this variable are based on a modified version of the ICD-10-CM alpha groupings as they are described in the official coding guidelines (Department of Health and Human Services, 2020). These classifications, as well as my modifications and any derivations from this coding rule, are described below:

Codes	ICD-10-CM Classification	Inclusion Notes
A00-B99	Certain infectious and parasitic diseases	Included as is.
C00-D49	Neoplasms	Included, but reimagined to 'Prevention of neoplasm.' Although these codes explicitly refer to oncological conditions, which were excluded from the review, some therapies in the included studies were for cancer prevention. These trials were still considered eligible.
D50-D89	Disease of the blood and blood-forming organs and certain disorders involving the immune mechanism	Included.
E00-E89	Endocrine, nutritional, and metabolic diseases	Included as is.

F01-F99	Mental, behavioral and neurodevelopmental Disorders	Included as is.
G00-G99	Diseases of the nervous system	Included as is.
H00-H59	Diseases of the eye and adnexa	Included as is.
H60-H95	Diseases of the ear and mastoid process	Included as is.
I00-I99	Diseases of the circulatory system	Included as is.
J00-J99	Diseases of the respiratory system	Included as is.
K00-K95	Diseases of the digestive system	Included as is.
L00-L99	Diseases of the skin and subcutaneous tissue	Included as is.
M00-M99	Diseases of the musculoskeletal system and connective tissue	Included as is.
N00-N99	Diseases of the genitourinary system	Included as is.
O00-O9A	Pregnancy, childbirth, and the puerperium	Included as is.
P00-P96	Certain conditions originating in the perinatal period	Included as is.
Q00-Q99	Congenital malformations, deformations, and chromosomal abnormalities	Included as is.
R00-R99	Symptoms, signs, and abnormal clinical laboratory findings, not elsewhere classified	Included as is.
S00-T88	Injury, poisoning, and certain other consequences of external causes	Included as is.
V00-Y99	External causes of morbidity	Excluded. These codes are explicitly for use in a clinical context, for particular patients and their circumstances (e.g., for specifying where an injury occured, or indicating a context of abuse or war). They are not necessary to include when coding indications for therapies in development.

Z00-Z99	Factors influencing health status and contact with health services	Included, but reimagined to 'Other general health and prevention' for therapeutic indications which do not fall into any previously described category. This category was necessary with two indications. The code Z33.1 (pregnant state, incidental) was used for contraceptive therapies for both sexes, and the code Z03.90 (encounter for observation for other suspected diseases and conditions ruled out) was used for supplements with numerous prophylactic uses.

Male or Female Specific Condition. Two additional binary variables related to the disease group were included as well, to code for whether or not the indication is sex-specific. These variables were independent variables, as they are expected to influence female participation. A condition was automatically coded as female-dominant if it was an obstetric code (beginning with O). If not, the 5th edition of the *International Statistical Classification of Diseases and Related Health Problems* (World Health Organization, 2011) was consulted. If the corresponding ICD-10 code appears on the "List of categories limited to, or more likely to occur in, female persons" (pp. 227-233), the condition was coded as female-specific. Likewise, a condition was coded as male-specific if the code appears on the "List of categories limited to, or more likely to occur in, male persons" (pp. 234). There was one derivation to this methodology in the case of contraceptive therapies. The code Z33.1 (pregnant state, incidental) was used for these trials, which is a female-specific code, however it was also used for male contraceptive therapies. In these cases, the variable was still coded as male-dominant.

Appendix C: Additional Tables and Figures

Appendix Table 1: The number of trials in each global region and an overview of which nations were represented.

Global Region	***n* (%)**
Africa	8 (2.1%)
South Africa	2 (0.5%)
Tanzania, United Republic of	2 (0.5%)
Egypt	1 (0.3%)
Gabon	1 (0.3%)
Gambia (the)	1 (0.3%)
Kenya	1 (0.3%)

Asia	64 (16.7%)
China	26 (6.8%)
Japan	25 (6.5%)
Korea (the Republic of)	4 (1%)
Iran (Islamic Republic of)	2 (0.5%)
Singapore	2 (0.5%)
Taiwan (Province of China)	2 (0.5%)
Bangladesh	1 (0.3%)
Hong Kong	1 (0.3%)
Indonesia	1 (0.3%)
Europe	90 (23.4%)
United Kingdom of Great Britain and Northern Ireland (the)	24 (6.3%)
Germany	16 (4.2%)
Belgium	14 (3.6%)
Netherlands (the)	13 (3.4%)
France	8 (2.1%)
Italy	3 (0.8%)
Spain	3 (0.8%)
Austria	2 (0.5%)
Romania	2 (0.5%)
Switzerland	2 (0.5%)
Czechia	1 (0.3%)
Denmark	1 (0.3%)
Norway	1 (0.3%)

The Americas	158 (41.1%)
United States of America (the)	145 (37.8%)
Canada	12 (3.1%)
Cuba	1 (0.3%)
Oceania	18 (4.7%)
Australia	17 (4.4%)
New Zealand	1 (0.3%)
Other	46 (12%)
Multiple countries	31 (8.1%)
Unknown	15 (3.9%)

Appendix Table 2: Trends in disease groups, specific conditions, and sex-specifitivity.

Indication	***n* (%)**
Certain infectious and parasitic diseases	99 (25.8%)
Endocrine, nutritional, and metabolic diseases	56 (14.6%)
Diseases of the nervous system	55 (14.3%)
Diseases of the respiratory system	26 (6.8%)
Diseases of the circulatory system	23 (6.0%)
Mental, behavioral and neurodevelopmental Disorders	19 (4.9%)
Disease of the blood and blood-forming organs and certain disorders involving the immune mechanism	18 (4.7%)
Diseases of the musculoskeletal system and connective tissue	17 (4.4%)
Diseases of the skin and subcutaneous tissue	13 (3.4%)
Diseases of the genitourinary system	11 (2.9%)
Diseases of the digestive system	9 (2.3%)
Injury, poisoning, and certain other consequences of external causes	6 (1.6%)

Certain conditions originating in the perinatal period	6 (1.6%)
Prevention of neoplasm.	3 (0.8%)
Diseases of the eye and adnexa	2 (0.5%)
Symptoms, signs, and abnormal clinical laboratory findings, not elsewhere classified	2 (0.5%)

Appendix Table 3: List of female-specific conditions

Code	Name of Indication	Total No.
D25.9	Leiomyoma of uterus, unspecified	1
N80.9	Endometriosis, unspecified	2
N95.1	Menopausal and female climacteric states	1
O24.419	Gestational diabetes mellitus in pregnancy, unspecified control	1
P35.1	Congenital cytomegalovirus infection	5
Z33.1	Pregnant state, incidental. Note that this code was used for female contraceptive devices.	1

Appendix Table 4: List of male-specific conditions.

Code	Name of Condition	Total No.
N41.1	Chronic prostatitis	1
Z33.1	Pregnant state, incidental. Note that this code was used for male contraceptive devices.	3

Appendix Table 5: Frequencies of different trial purposes.

Trial Purpose	% (N)
First-in-human trials	138 (35.9%)
Early clinical development studies (e.g., only safety, tolerability, PK or PD)	152 (39.6%)

Trials with therapeutic benefit for participation	83 (21.6%)
Trials comparing two or more drugs for the same indication	59 (15.4%)
Trials testing a drug-drug interaction	48 (12.5%)
Trials testing the effect of food	40 (10.4%)
Trials testing a new combination of two or more therapies	27 (7%)
Trials testing a therapy in a pediatric population	22 (5.7%)
Trials testing in new indication	15 (3.9%)
Trials testing on another disease population (not the indication)	14 (3.6%)
Trials testing the influence or effect of the therapy on renal impairment	13 (3.4%)
Trials testing on a race which has not been studied yet	12 (3.1%)
Trials testing in an elderly population	8 (2.1%)
Trials comparing the therapy on two or more races	6 (1.6%)
Trials testing the effect of or influence on hepatic impairment	6 (1.6%)
Trials testing the effect of other circumstances	5 (1.3%)
Trials testing in new setting/country	4 (1%)
Trials testing the effect of genetic polymorphisms	3 (0.8%)

Trials testing in gender which has not yet been tested	2 (0.5%)

Appendix Table 6: Frequencies of different trial endpoints.

Trial Endpoints	% (N)
Safety/Tolerability/TQT	334 (87%)
PK	288 (75%)
PD or Bioavailability	137 (35.7%)
Efficacy	107 (27.9%)
Bioequivalence	23 (6%)

Appendix Table 7: Frequencies of different routes of administration, therapy goals, market status and whether or not the therapy was a novel compound.

Route of Administration	% (N)
Oral tablet, capsule, or sublingual drops	195 (51%)
Injection	144 (37.7%)
Inhaler	9 (2.4%)
Multiple	9 (2.4%)
Topical cream/gel/serum	7 (1.8%)
Intranasal	4 (1%)

Transdermal	4 (1%)
Vaginal ring	4 (1%)
Intravesical	2 (0.5%)
Retinal injection	2 (0.5%)
Sinus irrigation	1 (0.3%)
Eye drops	1 (0.3%)
Goal	
To manage symptoms or prevent progression	243 (63.3%)
Prophylactic	76 (19.8%)
To fully cure	58 (15.1%)
Other or multiple	6 (1.6%)
To cure, and prophylactic	1 (0.3%)
Market Status	
Not approved	276 (71.9%)
Approved drug	91 (23.7%)
Supplement/OTC	17 (4.4%)

Novel Compound	
Yes	240 (62.5%)
No	144 (37.5%)

Appendix Table 8: Summary of the procedures performed in the trials, including blood draws and other procedures.

Blood Draws	
Studies involving at least one blood draw, *n* (%)	294 (76.7%)
No. of blood draws, range	0 to 240
No. of blood draws, mean	20.9
No. of blood draws, median	15
Additional Study Procedures	***n* (%)**
At least one instance of radiation exposure	7 (1.8%)
At least one cerebrospinal fluid collection	11 (2.9%)
At least one biopsy	11 (2.9%)
At least one scope procedure	10 (2.6%)
Purposeful malaria inoculation involved	5 (1.3%)
Pain testing involved	2 (0.5%)

Appendix Table 9: Enrollment for different racial groups across the five global regions.

Characteristic	**All**	**Africa**	**Americas**	**Asia**	**Europe**	**Oceania**	**Multiple**
Participants, total	18,636	1,403	7,497	3,079	4,338	970	1,349
White, % of total	45%	1%	52%	0%	77%	30%	54%
Middle Eastern, % of total	0%	0%	0%	2%	0%	0%	0%

Black, % of total	18%	88%	25%	0%	2%	1%	13%
Asian, % of total	15%	4%	4%	75%	2%	0%	11%
Native American, % of total	0%	0%	0%	0%	0%	0%	0%
Pacific Islander, % of total	0%	0%	0%	0%	0%	1%	0%
Multiracial, % of total	0%	0%	1%	0%	0%	0%	1%
Unknown race, % of total	21%	6%	18%	23%	19%	68%	21%

Appendix Table 10: Enrollment for different ethnic groups across the five global regions.

Characteristic	All	Africa	Americas	Asia	Europe	Oceania	Multiple
Participants, total	18,636	1,403	7,497	3,079	4,338	970	1,349
Hispanic, % of total	6%	0%	13%	0%	1%	1%	0%
Not Hispanic, % of total	24%	43%	37%	1%	18%	11%	6%
Unknown ethnicity, % of total	70%	54%	49%	95%	81%	88%	3%

Appendix Table 11: Summary of the number of trials with or without therapeutic benefit performed in each US region.

Trials with no therapeutic benefit				Trials with therapeutic benefit			
US Region				US Region			
Northeast Count	Midwest Count	South Count	West Count	Northeast Count	Midwest Count	South Count	West Count
25	28	25	14	10	2	1	0

Appendix C: All Eligible Articles and Trials

Study ID	Authors	Article Title
690160	Forster CS and Hsieh MH and PÃ©rez-Losada M and Caldovic L and Pohl H and Ljungberg I and Sprague B and Stroud C and Groah S	A single intravesical instillation of Lactobacillus rhamnosus GG is safe in children and adults with neuropathic bladder: A phase Ia clinical trial.
690201	Rizea-Savu S and Duna SN and Ghita A and Iordachescu A and Chirila M	The Effect of Food on the Single-Dose Bioavailability and Tolerability of the Highest Marketed Strength of Duloxetine.
690202	Rizea-Savu S and Duna SN and Ghita A and Iordachescu A and Chirila M	The Effect of Food on the Single-Dose Bioavailability and Tolerability of the Highest Marketed Strength of Duloxetine.
690400	Wang M and Zhou W and Zhang Q and Zong S and Lv C	Pharmacokinetics, Pharmacodynamics, and Safety of a Single Escalating Dose and Repeated Doses of Rasagiline Transdermal Patch in Healthy Chinese Subjects.
690411	Nafziger AN and Arscott KA and Cochrane K and Skobieranda F and Burt DA and Fossler MJ	The Influence of Renal or Hepatic Impairment on the Pharmacokinetics, Safety, and Tolerability of Oliceridine.
690412	Nafziger AN and Arscott KA and Cochrane K and Skobieranda F and Burt DA and Fossler MJ	The Influence of Renal or Hepatic Impairment on the Pharmacokinetics, Safety, and Tolerability of Oliceridine.
690450	Yendewa GA and Griffiss JM and Jacobs MR and Fulton SA and O'Riordan MA and Gray WA and Proskin HM and Winkle P and Salata RA	A two-part phase 1 study to establish and compare the safety and local tolerability of two nasal formulations of XF-73 for decolonisation of Staphylococcus aureus: A previously investigated 0.5mg/g viscosified gel formulation versus a modified formulation.
690560	Flanagan S and Goodman DB and Jandourek A and O'Reilly T and Sandison T	Lack of Effect of Rezafungin on QT/QTc Interval in Healthy Subjects.
690570	Knight-Perry J and Jennissen C and Long SE and Hage S and DeFor TE and Chan WT and Fisher J and Kirstein MN and Smith AR	A phase I dose finding study of intravenous voriconazole in pediatric patients undergoing hematopoietic cell transplantation.
690600	Shimada H and Yono M and Hojo Y and Hamamura Y and Ootsuki A	Phase I study of KRP-116D, a 50.0% w/w dimethyl sulfoxide aqueous solution, on the systemic absorption from bladder by intravesical instillation in healthy Japanese subjects.
690610	Lu L and Ryan M and Harnett M and Atiee GJ and Reines SA	Comparing the Pharmacokinetics of 2 Novel Intravenous Tramadol Dosing Regimens to Oral Tramadol: A Randomized 3-Arm Crossover Study.
690621	Li X and Liu J and Sheng C and Chen H and Cui D and Chen G and Zhang H and Zhu X and Wu M and Li C and Shen Z and Guo Y and Ding Y and Jiao Z	Clinical Evaluation of the Tolerability and Pharmacokinetics of Azilsartan, a Potent Angiotensin Receptor Blocker, in Healthy Chinese Subjects.
690622	Li X and Liu J and Sheng C and Chen H and Cui D and Chen G and Zhang H and Zhu X and Wu M and Li C and Shen Z and Guo Y and Ding Y and Jiao Z	Clinical Evaluation of the Tolerability and Pharmacokinetics of Azilsartan, a Potent Angiotensin Receptor Blocker, in Healthy Chinese Subjects.
690650	Kushner J 4th and Lamba M and Stock T and Wang R and Nemeth MA and Alvey C and Chen R and DeMatteo V and Blanchard A	Development and validation of a Level A in-vitro in-vivo correlation for tofacitinib modified-release tablets using extrudable core system osmotic delivery technology.
690710	Ericsson H and Nelander K and Heijer M and Kjaer M and Lindstedt EL and Albayaty M and Forte P and LagerstrÃ¶m-FermÃ©r M and Skrtic S	Phase 1 Pharmacokinetic Study of AZD5718 in Healthy Volunteers: Effects of Coadministration With Rosuvastatin, Formulation and Food on Oral Bioavailability.
690730	Shuster DL and Shireman LM and Ma X and Shen DD and Flood Nichols SK and Ahmed MS and Clark S and Caritis S and Venkataramanan R and Haas DM and Quinney SK and Haneline LS and Tita AT and Manuck TA and Thummel KE and Morris	Pharmacodynamics of Metformin in Pregnant Women With Gestational Diabetes Mellitus and Nonpregnant Women With Type 2 Diabetes Mellitus.

	Brown L and Ren Z and Brown Z and Easterling TR and Hebert MF	
690750	Jakate A and Boinpally R and Butler M and Lu K and McGeeney D and Periclou A	Single Therapeutic and Supratherapeutic Doses of Ubrogepant Do Not Affect Cardiac Repolarization in Healthy Adults: Results From a Randomized Trial.
690780	Yumizaki T and Maeda M and Fujita T and Kakuyama H and Kumagai Y	A 3-Part Phase 1 Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of DSP-6952 in Healthy Japanese Subjects and Those With â‰¤3 Spontaneous Bowel Movements per Week.
690811	Hazan Z and Adamsky K and Lucassen A and Levin LA	A First-in-Human Phase 1 Randomized Single and Multiple Ascending Dose Study of RPh201 in Healthy Volunteers.
690812	Hazan Z and Adamsky K and Lucassen A and Levin LA	A First-in-Human Phase 1 Randomized Single and Multiple Ascending Dose Study of RPh201 in Healthy Volunteers.
691031	Totsuka K and Sesoko S and Fukase H and Ikushima I and Odajima M and Niwayama Y	Pharmacokinetic study of lascufloxacin in non-elderly healthy men and elderly men.
691032	Totsuka K and Sesoko S and Fukase H and Ikushima I and Odajima M and Niwayama Y	Pharmacokinetic study of lascufloxacin in non-elderly healthy men and elderly men.
691033	Totsuka K and Sesoko S and Fukase H and Ikushima I and Odajima M and Niwayama Y	Pharmacokinetic study of lascufloxacin in non-elderly healthy men and elderly men.
691034	Totsuka K and Sesoko S and Fukase H and Ikushima I and Odajima M and Niwayama Y	Pharmacokinetic study of lascufloxacin in non-elderly healthy men and elderly men.
691035	Totsuka K and Sesoko S and Fukase H and Ikushima I and Odajima M and Niwayama Y	Pharmacokinetic study of lascufloxacin in non-elderly healthy men and elderly men.
691041	Sheng XY and Liang Y and Yang XY and Li LE and Ye X and Zhao X and Cui YM	Safety, pharmacokinetic and pharmacodynamic properties of single ascending dose and continuous infusion of remimazolam besylate in healthy Chinese volunteers.
691042	Sheng XY and Liang Y and Yang XY and Li LE and Ye X and Zhao X and Cui YM	Safety, pharmacokinetic and pharmacodynamic properties of single ascending dose and continuous infusion of remimazolam besylate in healthy Chinese volunteers.
691191	Becker A and Martin EC and Mitchell DY and Grenningloh R and Bender AT and Laurent J and Mackenzie H and Johne A	Safety, Tolerability, Pharmacokinetics, Target Occupancy, and Concentration-QT Analysis of the Novel BTK Inhibitor Evobrutinib in Healthy Volunteers.
691192	Becker A and Martin EC and Mitchell DY and Grenningloh R and Bender AT and Laurent J and Mackenzie H and Johne A	Safety, Tolerability, Pharmacokinetics, Target Occupancy, and Concentration-QT Analysis of the Novel BTK Inhibitor Evobrutinib in Healthy Volunteers.
691200	Siebenga P and van Amerongen G and Hay JL and McDonnell A and Gorman D and Butt R and Groeneveld GJ	Lack of Detection of the Analgesic Properties of PF-05089771, a Selective Na(v) 1.7 Inhibitor, Using a Battery of Pain Models in Healthy Subjects.
691260	Koller D and Belmonte C and Saiz-RodrÃguez M and Zubiaur P and RomÃ¡n M and Ochoa D and Abad-Santos F	Effects of aripiprazole on circadian prolactin secretion related to pharmacogenetics in healthy volunteers.
691350	Duthie MS and Frevol A and Day T and Coler RN and Vergara J and Rolf T and Sagawa ZK and Marie Beckmann A and Casper C and Reed SG	A phase 1 antigen dose escalation trial to evaluate safety, tolerability and immunogenicity of the leprosy vaccine candidate LepVax (LEP-F1Â +Â GLA-SE) in healthy adults.
691360	Pastural E and McNeil SA and MacKinnon-Cameron D and Ye L and Langley JM and Stewart R and Martin LH and Hurley GJ and Salehi S and Penfound TA and Halperin S and Dale JB	Safety and immunogenicity of a 30-valent M protein-based group a streptococcal vaccine in healthy adult volunteers: A randomized, controlled phase I study.
691401	Li J and Chen J and Kanamaluru V and Gaemers SJM and Peterschmitt MJ and Hou AW and Xue Y and Turpault S and Rudin D	Impact of hepatic and renal impairment on the pharmacokinetics and tolerability of eliglustat therapy for Gaucher disease type 1.
691402	Li J and Chen J and Kanamaluru V and Gaemers SJM and Peterschmitt MJ and Hou AW and Xue Y and Turpault S and Rudin D	Impact of hepatic and renal impairment on the pharmacokinetics and tolerability of eliglustat therapy for Gaucher disease type 1.
691440	Dunn LJ and Kerwin EM and DeAngelis K and Darken P and Gillen M and Dorinsky P	Pharmacokinetics of budesonide/glycopyrrolate/formoterol fumarate metered dose inhaler formulated using co-suspension

		delivery technology after single and chronic dosing in patients with COPD.
691460	Zhang H and Wu M and Zhu X and Li C and Li X and Jin W and Zhang D and Chen H and Liu C and Ding Y and Niu J and Liu J	Safety, efficacy, and pharmacokinetics of pradefovir for the treatment of chronic hepatitis B infection.
691520	Slifstein M and Abi-Dargham A and Girgis RR and Suckow RF and Cooper TB and Divgi CR and Sokoloff P and Leriche L and Carberry P and Oya S and Joseph SK and Guiraud M and Montagne A and Brunner V and Gaudoux F and Tonner F	Binding of the D3-preferring antipsychotic candidate F17464 to dopamine D3 and D2 receptors: a PET study in healthy subjects with [(11)C]-(+)-PHNO.
691630	Mohseni AH and Taghinezhad-S S and Keyvani H	The First Clinical Use of a Recombinant Lactococcus lactis Expressing Human Papillomavirus Type 16 E7 Oncogene Oral Vaccine: A Phase I Safety and Immunogenicity Trial in Healthy Women Volunteers.
691750	Mohamed MF and Beck D and Camp HS and Othman AA	Preferential Inhibition of JAK1 Relative to JAK3 by Upadacitinib: Exposure-Response Analyses of Ex Vivo Data From 2 Phase 1 Clinical Trials and Comparison to Tofacitinib.
691761	Grievink HW and Heuberger JAAC and Huang F and Chaudhary R and Birkhoff WAJ and Tonn GR and Mosesova S and Erickson R and Moerland M and Haddick PCG and Scearce-Levie K and Ho C and Groeneveld GJ	DNL104, a Centrally Penetrant RIPK1 Inhibitor, Inhibits RIP1 Kinase Phosphorylation in a Randomized Phase I Ascending Dose Study in Healthy Volunteers.
691762	Grievink HW and Heuberger JAAC and Huang F and Chaudhary R and Birkhoff WAJ and Tonn GR and Mosesova S and Erickson R and Moerland M and Haddick PCG and Scearce-Levie K and Ho C and Groeneveld GJ	DNL104, a Centrally Penetrant RIPK1 Inhibitor, Inhibits RIP1 Kinase Phosphorylation in a Randomized Phase I Ascending Dose Study in Healthy Volunteers.
691790	Chen J and Lou H and Jiang B and Shao R and Yang D and Hu Y and Xu Y and Ruan Z	Effects of Food and Gender on Pharmacokinetics of Rosuvastatin in a Chinese Population Based on 4 Bioequivalence Studies.
691850	Khoo JK and Montgomery AB and Otto KL and Surber M and Faggian J and Lickliter JD and Glaspole I	A Randomized, Double-Blinded, Placebo-Controlled, Dose-Escalation Phase 1 Study of Aerosolized Pirfenidone Delivered via the PARI Investigational eFlow Nebulizer in Volunteers and Patients with Idiopathic Pulmonary Fibrosis.
691860	Wilkie M and Satti I and Minhinnick A and Harris S and Riste M and Ramon RL and Sheehan S and Thomas ZM and Wright D and Stockdale L and Hamidi A and O'Shea MK and Dwivedi K and Behrens HM and Davenne T and Morton J and Vermaak S and Lawrie A and Moss P and McShane H	A phase I trial evaluating the safety and immunogenicity of a candidate tuberculosis vaccination regimen, ChAdOx1 85A prime - MVA85A boost in healthy UK adults.
691870	Otten G and Matassa V and Ciarlet M and Leav B	A phase 1, randomized, observer blind, antigen and adjuvant dosage finding clinical trial to evaluate the safety and immunogenicity of an adjuvanted, trivalent subunit influenza vaccine in adultsâ€¯â‰¥â€¯65 years of age.
691920	Clarke E and Bashorun AO and Okoye M and Umesi A and Badjie Hydara M and Adigweme I and Dhere R and Sethna V and Kampmann B and Goldblatt D and Tate A and Weiner DH and Flores J and Alderson MR and Lamola S	Safety and immunogenicity of a novel 10-valent pneumococcal conjugate vaccine candidate in adults, toddlers, and infants in The Gambia-Results of a phase 1/2 randomized, double-blinded, controlled trial.
691960	Portron A and Jordan P and Draper K and Muenzer C and Dickerson D and van Iersel T and Hofmann C	A Phase I Study to Assess the Effect of Speed of Injection on Pain, Tolerability, and Pharmacokinetics After High-volume Subcutaneous Administration of Gantenerumab in Healthy Volunteers.

691980	Anderson K and Xin Y and Zheng H and Yun C and Kwan E and Qin A and Namour F and Kearney BP and Mathias A	Filgotinib, a JAK1 Inhibitor, Has No Effect on QT Interval in Healthy Subjects.
692030	Tiede A and Allen G and Bauer A and Chowdary P and Collins P and Goldstein B and Jiang HJ and KÓ§ck K and TakÃ¡cs I and Timofeeva M and Wolfsegger M and Srivastava S	SHP656, a polysialylated recombinant factor VIII (PSA-rFVIII): First-in-human study evaluating safety, tolerability and pharmacokinetics in patients with severe haemophilia A.
692060	Aslam MN and Bassis CM and Bergin IL and Knuver K and Zick SM and Sen A and Turgeon DK and Varani J	A Calcium-Rich Multimineral Intervention to Modulate Colonic Microbial Communities and Metabolomic Profiles in Humans: Results from a 90-Day Trial.
692110	Miyoshi S and Krishnaswami S and Toyoizumi S and Nakamura H and Zwillich SH	Phase 1 Dose-Escalation Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Tofacitinib in Japanese Healthy Volunteers.
692150	Phetkate P and Kummalue T and Rinthong PO and Kietinun S and Sriyakul K	Study of the safety of oral Triphala aqueous extract on healthy volunteers.
692160	Jiang Y and Zhang Y and Xiang S and Zhao W and Liu J and Zhang W	Safety, tolerability, and pharmacokinetics of adamgammadex sodium, a novel agent to reverse the action of rocuronium and vecuronium, in healthy volunteers.
692181	Richard F and van Lier JJ and Roubert B and Haboubi T and GÃ¶hring UM and DÃ¼rrenberger F	Oral ferroportin inhibitor VIT-2763: First-in-human, phase 1 study in healthy volunteers.
692182	Richard F and van Lier JJ and Roubert B and Haboubi T and GÃ¶hring UM and DÃ¼rrenberger F	Oral ferroportin inhibitor VIT-2763: First-in-human, phase 1 study in healthy volunteers.
692200	Bouhajib M and Tayab Z	A Pharmacokinetic Evaluation of Dabigatran Etexilate, Total Dabigatran, and Unconjugated Dabigatran Following the Administration of Dabigatran Etexilate Mesylate Capsules in Healthy Male and Female Subjects.
692210	Dunbar J and Versavel M and Zhao Y and Tate S and Morisset V and Giblin GMP and Palmer J and Tidemann-Miller B and Naik H	Evaluation of the Pharmacokinetic Interaction Between the Voltage- and Use-Dependent Nav1.7 Channel Blocker Vixotrigine and Carbamazepine in Healthy Volunteers.
692240	Bernstein DI and Guptill J and Naficy A and Nachbagauer R and Berlanda-Scorza F and Feser J and Wilson PC and SolÃ³rzano A and Van der Wielen M and Walter EB and Albrecht RA and Buschle KN and Chen YQ and Claeys C and Dickey M and Dugan HL and Ermler ME and Freeman D and Gao M and Gast C and Guthmiller JJ and Hai R and Henry C and Lan LY and McNeal M and Palm AE and Shaw DG and Stamper CT and Sun W and Sutton V and Tepora ME and Wahid R and Wenzel H and Wohlbold TJ and Innis BL and GarcÃa-Sastre A and Palese P and Krammer F	Immunogenicity of chimeric haemagglutinin-based, universal influenza virus vaccine candidates: interim results of a randomised, placebo-controlled, phase 1 clinical trial.
692270	Xu L and Zhang Y and Xue X and Liu J and Li ZS and Yang GY and Song Y and Pan Y and Ma Y and Hu S and Wen A and Jia Y and Rodriguez LM and Tull MB and Benante K and Khan SA and Cao Y and Jovanovic B and Richmond E and Umar A and Bergan R and Wu K	A Phase I Trial of Berberine in Chinese with Ulcerative Colitis.
692521	Dawra VK and Liang Y and Wei H and Pelletier K and Shi H and Hickman A and Bass A and Terra SG and Zhou S and Krishna R and Sahasrabudhe V	Bioequivalence of Ertugliflozin/Metformin Fixed-Dose Combination Tablets and Coadministration of Respective Strengths of Individual Components.

692522	Dawra VK and Liang Y and Wei H and Pelletier K and Shi H and Hickman A and Bass A and Terra SG and Zhou S and Krishna R and Sahasrabudhe V	Bioequivalence of Ertugliflozin/Metformin Fixed-Dose Combination Tablets and Coadministration of Respective Strengths of Individual Components.
692523	Dawra VK and Liang Y and Wei H and Pelletier K and Shi H and Hickman A and Bass A and Terra SG and Zhou S and Krishna R and Sahasrabudhe V	Bioequivalence of Ertugliflozin/Metformin Fixed-Dose Combination Tablets and Coadministration of Respective Strengths of Individual Components.
692524	Dawra VK and Liang Y and Wei H and Pelletier K and Shi H and Hickman A and Bass A and Terra SG and Zhou S and Krishna R and Sahasrabudhe V	Bioequivalence of Ertugliflozin/Metformin Fixed-Dose Combination Tablets and Coadministration of Respective Strengths of Individual Components.
692580	Bush J and Kawakami K and Muniz R	A phase 1, randomized, open-label, single-dose study to assess the relative bioavailability of a subcutaneous dose of FKB327 when administered using a prefilled syringe, a prefilled auto-injector, or a vial with disposable syringe in healthy subjects.
692630	McCarthy JS and RÃ¼ckle T and Elliott SL and Ballard E and Collins KA and Marquart L and Griffin P and Chalon S and MÃ¶hrle JJ	A Single-Dose Combination Study with the Experimental Antimalarials Artefenomel and DSM265 To Determine Safety and Antimalarial Activity against Blood-Stage Plasmodium falciparum in Healthy Volunteers.
692660	Herold KC and Bucktrout SL and Wang X and Bode BW and Gitelman SE and Gottlieb PA and Hughes J and Joh T and McGill JB and Pettus JH and Potluri S and Schatz D and Shannon M and Udata C and Wong G and Levisetti M and Ganguly BJ and Garzone PD	Immunomodulatory activity of humanized anti-IL-7R monoclonal antibody RN168 in subjects with type 1 diabetes.
692680	Holguin F and Grasemann H and Sharma S and Winnica D and Wasil K and Smith V and Cruse MH and Perez N and Coleman E and Scialla TJ and Que LG	L-Citrulline increases nitric oxide and improves control in obese asthmatics.
692690	Blumberg LJ and Humphries JE and Jones SD and Pearce LB and Holgate R and Hearn A and Cheung J and Mahmood A and Del Tito B and Graydon JS and Stolz LE and Bitonti A and Purohit S and de Graaf D and Kacena K and Andersen JT and Christianson GJ and Roopenian DC and Hubbard JJ and Gandhi AK and Lasseter K and Pyzik M and Blumberg RS	Blocking FcRn in humans reduces circulating IgG levels and inhibits IgG immune complex-mediated immune responses.
692700	Chandra J and Woo WP and Dutton JL and Xu Y and Li B and Kinrade S and Druce J and Finlayson N and Griffin P and Laing KJ and Koelle DM and Frazer IH	Immune responses to a HSV-2 polynucleotide immunotherapy COR-1 in HSV-2 positive subjects: A randomized double blinded phase I/IIa trial.
692741	Pons L and Vilain C and Volteau M and Picaut P	Safety and pharmacodynamics of a novel recombinant botulinum toxin E (rBoNT-E): Results of a phase 1 study in healthy male subjects compared with abobotulinumtoxinA (DysportÂ®).
692742	Pons L and Vilain C and Volteau M and Picaut P	Safety and pharmacodynamics of a novel recombinant botulinum toxin E (rBoNT-E): Results of a phase 1 study in healthy male subjects compared with abobotulinumtoxinA (DysportÂ®).
692830	Yi JM and Bang JY and Choi B and Cho C and Lee YH and Lee EK and Choi BM and Noh GJ	Population-based volume kinetics of crystalloids and colloids in healthy volunteers.
692840	Wang J and Huang J and Yang S and Cui C and Ye L and Wang SY and Yang GP and Pei Q	Pharmacokinetics and Safety of Esketamine in Chinese Patients Undergoing Painless Gastroscopy in Comparison with Ketamine: A Randomized, Open-Label Clinical Study.
692851	Danto SI and Shojaee N and Singh RSP and Li C and Gilbert SA and Manukyan Z and Kilty I	Safety, tolerability, pharmacokinetics, and pharmacodynamics of PF-06650833, a selective interleukin-1 receptor-associated kinase 4 (IRAK4) inhibitor, in single and multiple ascending dose randomized phase 1 studies in healthy subjects.

692852	Danto SI and Shojaee N and Singh RSP and Li C and Gilbert SA and Manukyan Z and Kilty I	Safety, tolerability, pharmacokinetics, and pharmacodynamics of PF-06650833, a selective interleukin-1 receptor-associated kinase 4 (IRAK4) inhibitor, in single and multiple ascending dose randomized phase 1 studies in healthy subjects.
692900	Sun JK and Maturi RK and Boyer DS and Wells JA and Gonzalez VH and Tansley R and Hernandez H and Maetzel A and Feener EP and Aiello LP	One-Time Intravitreal Injection of KVD001, a Plasma Kallikrein Inhibitor, in Patients with Central-Involved Diabetic Macular Edema and Reduced Vision: An Open-Label Phase 1B Study.
693060	Marshall HS and Baber J and Richmond P and Nissen M and Shakib S and Kreiswirth BN and Zito ET and Severs J and Eiden J and Gruber W and Jansen KU and Jones CH and Anderson AS	S. aureus colonization in healthy Australian adults receiving an investigational S. aureus 3-antigen vaccine.
693120	Boffa MB and Marar TT and Yeang C and Viney NJ and Xia S and Witztum JL and Koschinsky ML and Tsimikas S	Potent reduction of plasma lipoprotein (a) with an antisense oligonucleotide in human subjects does not affect ex vivo fibrinolysis.
693160	Goadsby PJ and Tepper SJ and Watkins PB and Ayele G and Miceli R and Butler M and Severt L and Finnegan M and Szegedi A and Trugman JM and Jakate A	Safety and tolerability of ubrogepant following intermittent, high-frequency dosing: Randomized, placebo-controlled trial in healthy adults.
693190	Liu Y and Freed DC and Li L and Tang A and Li F and Murray EM and Adler SP and McVoy MA and Rupp RE and Barrett D and Ye X and Zhang N and Beck K and Culp T and Das R and Song L and Vora K and Zhu H and Wang D and Espeseth AS and An Z and Musey L and Fu TM	A Replication-Defective Human Cytomegalovirus Vaccine Elicits Humoral Immune Responses Analogous to Those with Natural Infection.
693250	Gonzalez D and Laughon MM and Smith PB and Ge S and Ambalavanan N and Atz A and Sokol GM and Hornik CD and Stewart D and Mundakel G and Poindexter BB and Gaedigk R and Mills M and Cohen-Wolkowiez M and Martz K and Hornik CP	Population pharmacokinetics of sildenafil in extremely premature infants.
693270	Ooi ML and Jothin A and Bennett C and Ooi EH and Vreugde S and Psaltis AJ and Wormald PJ	Manuka honey sinus irrigations in recalcitrant chronic rhinosinusitis: phase 1 randomized, single-blinded, placebo-controlled trial.
693300	Thurman A and Cunningham T and Fichorova R and Herold BC and Hillier SL and Chandra N and Doncel GF	A phase I randomized safety study of a single-size silicone rubber diaphragm used with or without a lactic-acid-containing diaphragm gel.
693401	Zhou J and Limsakun T and Yin O and Warren V and Zamora C and Atiee G and Kochan J and Pav J and Kobayashi F and Vashi V and Dishy V	First-in-Human Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of an Oral Formulation of DS-1040, an Inhibitor of the Activated Form of Thrombin-Activatable Fibrinolysis Inhibitor, in Healthy Subjects.
693402	Zhou J and Limsakun T and Yin O and Warren V and Zamora C and Atiee G and Kochan J and Pav J and Kobayashi F and Vashi V and Dishy V	First-in-Human Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of an Oral Formulation of DS-1040, an Inhibitor of the Activated Form of Thrombin-Activatable Fibrinolysis Inhibitor, in Healthy Subjects.
693420	Freire PC and MuÃ±oz CH and Derhaschnig U and Schoergenhofer C and Firbas C and Parry GC and Panicker S and Gilbert JC and Stingl G and Jilma B and Heil PM	Specific Inhibition of the Classical ComplementÂ Pathway Prevents C3 DepositionÂ along the Dermal-Epidermal Junction in BullousÂ Pemphigoid.
693530	Tawfik MS and Abdel-Ghaffar KA and Gamal AY and El-Demerdash FH and Gad HA	Lycopene solid lipid microparticles with enhanced effect on gingival crevicular fluid protein carbonyl as a biomarker of oxidative stress in patients with chronic periodontitis.
693590	Niikura T and Iwakura T and Omori T and Lee SY and Sakai Y and Akisue T and Oe K and Fukui T and Matsushita T and Matsumoto T and Kuroda R	Topical cutaneous application of carbon dioxide via a hydrogel for improved fracture repair: results of phase I clinical safety trial.

693630	Meyers T and Samson P and Acosta EP and Moye J and Townley E and Bradford S and Marillo L and Denson K and Hovind L and Sise T and Teppler H and Mathiba SR and Masenya M and Hesseling A and Cotton MF and Krogstad P	Pharmacokinetics and safety of a raltegravir-containing regimen in HIV-infected children aged 2-12 years on rifampicin for tuberculosis.
693720	Prothon S and WÃ¤hlby HamrÃ©n U and Tehler U and Yoon E and Forsman H and Arfvidsson C and Aggarwal A and Chen Y	Safety, pharmacokinetics and pharmacodynamics of the selective glucocorticoid receptor modulator AZD7594, following inhalation in healthy Japanese volunteers.
693890	Pantaleo G and Janes H and Karuna S and Grant S and Ouedraogo GL and Allen M and Tomaras GD and Frahm N and Montefiori DC and Ferrari G and Ding S and Lee C and Robb ML and Esteban M and Wagner R and Bart PA and Rettby N and McElrath MJ and Gilbert PB and Kublin JG and Corey L	Safety and immunogenicity of a multivalent HIV vaccine comprising envelope protein with either DNA or NYVAC vectors (HVTN 096): a phase 1b, double-blind, placebo-controlled trial.
693920	Premoli I and Rossini PG and Goldberg PY and Posadas K and Green L and Yogo N and Pimstone S and Abela E and Beatch GN and Richardson MP	TMS as a pharmacodynamic indicator of cortical activity of a novel anti-epileptic drug, XEN1101.
693930	Rouphael NG and Morgan C and Li SS and Jensen R and Sanchez B and Karuna S and Swann E and Sobieszczyk ME and Frank I and Wilson GJ and Tieu HV and Maenza J and Norwood A and Kobie J and Sinangil F and Pantaleo G and Ding S and McElrath MJ and De Rosa SC and Montefiori DC and Ferrari G and Tomaras GD and Keefer MC	DNA priming and gp120 boosting induces HIV-specific antibodies in a randomized clinical trial.
694010	Rappo U and Dunne MW and Puttagunta S and Baldassarre JS and Su S and Desai-Krieger D and Inoue M	Epithelial Lining Fluid and Plasma Concentrations of Dalbavancin in Healthy Adults after a Single 1,500-Milligram Infusion.
694090	Sidharta PN and UlÄ I and Dingemanse J	Single-Dose Pharmacokinetics and Tolerability of Aprocitentan, a Dual Endothelin Receptor Antagonist, in Subjects with Severe Renal Function Impairment.
694100	Li H and Wei Y and Zhang S and Xu L and Jiang J and Qiu Y and Mangin E and Zhao XM and Xie S	Pharmacokinetics and Safety of Posaconazole Administered by Intravenous Solution and Oral Tablet in Healthy Chinese Subjects and Effect of Food on Tablet Bioavailability.
694110	Mammen MP and Armas D and Hughes FH and Hopkins AM and Fisher CL and Resch PA and Rusalov D and Sullivan SM and Smith LR	First-in-Human Phase 1 Study To Assess Safety, Tolerability, and Pharmacokinetics of a Novel Antifungal Drug, VL-2397, in Healthy Adults.
694200	Nishida C and Matsumoto Y and Fujimoto K and Shirakawa M and Wrishko RE and Behm MO and Furihata K	The Bioequivalence and Effect of Food on the Pharmacokinetics of a Fixed-Dose Combination Tablet Containing Rosuvastatin and Ezetimibe in Healthy Japanese Subjects.
694231	Garner RM and Mould DR and Chieffo C and Jorkasky DK	Pharmacokinetic and Pharmacodynamic Effects of Oral CXA-10, a NitroÂ Fatty Acid, After Single and Multiple Ascending Doses in Healthy and Obese Subjects.
694232	Garner RM and Mould DR and Chieffo C and Jorkasky DK	Pharmacokinetic and Pharmacodynamic Effects of Oral CXA-10, a NitroÂ Fatty Acid, After Single and Multiple Ascending Doses in Healthy and Obese Subjects.
694233	Garner RM and Mould DR and Chieffo C and Jorkasky DK	Pharmacokinetic and Pharmacodynamic Effects of Oral CXA-10, a NitroÂ Fatty Acid, After Single and Multiple Ascending Doses in Healthy and Obese Subjects.
694260	Gane E and Verdon DJ and Brooks AE and Gaggar A and Nguyen AH and Subramanian GM and Schwabe C and Dunbar PR	Anti-PD-1 blockade with nivolumab with and without therapeutic vaccination for virally suppressed chronic hepatitis B: A pilot study.
694340	Lee HA and Yu KS and Park SI and Yoon S and Onohara M and Ahn Y and Lee H	URC102, a potent and selective inhibitor of hURAT1, reduced serum uric acid in healthy volunteers.

694461	Ng J and Duan WR and Marbury T and Schmidt JM and Klein CE	Elagolix Pharmacokinetic Profiles in Women With Renal or Hepatic Impairment.
694462	Ng J and Duan WR and Marbury T and Schmidt JM and Klein CE	Elagolix Pharmacokinetic Profiles in Women With Renal or Hepatic Impairment.
694470	Mohamed MF and Trueman S and Othman AA and Han JH and Ju TR and Marroum P	Development of In Vitro-In Vivo Correlation for Upadacitinib Extended-Release Tablet Formulation.
694570	Mordmuller B and Sulyok M and Egger-Adam D and Resende M and de Jongh WA and Jensen MH and Smedegaard HH and Ditlev SB and Soegaard M and Poulsen L and Dyring C and Calle CL and Knoblich A and IbÃ¡Ã±ez J and Esen M and Deloron P and Ndam N and Issifou S and Houard S and Howard RF and Reed SG and Leroy O and Luty AJF and Theander TG and Kremsner PG and Salanti A and Nielsen MA	First-in-human, Randomized, Double-blind Clinical Trial of Differentially Adjuvanted PAMVAC, A Vaccine Candidate to Prevent Pregnancy-associated Malaria.
694600	Keitel WA and Potter GE and Diemert D and Bethony J and El Sahly HM and Kennedy JK and Patel SM and Plieskatt JL and Jones W and Deye G and Bottazzi ME and Hotez PJ and Atmar RL	A phase 1 study of the safety, reactogenicity, and immunogenicity of a Schistosoma mansoni vaccine with or without glucopyranosyl lipid A aqueous formulation (GLA-AF) in healthy adults from a non-endemic area.
694780	Gaudinski MR and Houser KV and Doria-Rose NA and Chen GL and Rothwell RSS and Berkowitz N and Costner P and Holman LA and Gordon IJ and Hendel CS and Kaltovich F and Conan-Cibotti M and Gomez Lorenzo M and Carter C and Sitar S and Carlton K and Gall J and Laurencot C and Lin BC and Bailer RT and McDermott AB and Ko SY and Pegu A and Kwon YD and Kwong PD and Namboodiri AM and Pandey JP and Schwartz R and Arnold F and Hu Z and Zhang L and Huang Y and Koup RA and Capparelli EV and Graham BS and Mascola JR and Ledgerwood JE	Safety and pharmacokinetics of broadly neutralising human monoclonal antibody VRC07-523LS in healthy adults: a phase 1 dose-escalation clinical trial.
694841	Han S and Choi HY and Kim YH and Nam JY and Kim B and Song GS and Lim HS and Bae KS	Randomised clinical trial: safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple oral doses of tegoprazan (CJ-12420), a novel potassium-competitive acid blocker, in healthy male subjects.
694842	Han S and Choi HY and Kim YH and Nam JY and Kim B and Song GS and Lim HS and Bae KS	Randomised clinical trial: safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple oral doses of tegoprazan (CJ-12420), a novel potassium-competitive acid blocker, in healthy male subjects.
694843	Han S and Choi HY and Kim YH and Nam JY and Kim B and Song GS and Lim HS and Bae KS	Randomised clinical trial: safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple oral doses of tegoprazan (CJ-12420), a novel potassium-competitive acid blocker, in healthy male subjects.
694920	Abraham S and Juel HB and Bang P and Cheeseman HM and Dohn RB and Cole T and Kristiansen MP and Korsholm KS and Lewis D and Olsen AW and McFarlane LR and Day S and Knudsen S and Moen K and Ruhwald M and Kromann I and Andersen P and Shattock RJ and Follmann F	Safety and immunogenicity of the chlamydia vaccine candidate CTH522 adjuvanted with CAF01 liposomes or aluminium hydroxide: a first-in-human, randomised, double-blind, placebo-controlled, phase 1 trial.
694930	Wang Q and Xie X and Su F and Wang J and Chen S and Wang Q and Jiang D and Wang Y and Zhang T and Liu C and Han M and Tao T and Wu Q and Xi N and Li Z and Song H and Fang Y	A randomized controlled dose-escalation study of SSS07, a humanized rabbit anti-human TNF alpha antibody, in healthy Chinese adults.

694980	Jones NS and Winter H and Katsumoto TR and Florero M and Murray E and Walker H and Singh N and Chinn LW	Absence of Pharmacokinetic Interactions between the Bruton's Tyrosine Kinase Inhibitor Fenebrutinib and Methotrexate.
695030	Preston RA and Mamikonyan G and Mastim M and Garg D and Kemper CJ and Xu A and Yeole R and Chavan R and Friedland HD and Bhatia A	Single-Center Investigation of the Pharmacokinetics of WCK 4282 (Cefepime-Tazobactam Combination) in Renal Impairment.
695081	Couroux P and Farias P and Rizvi L and Griffin K and Hudson C and Crowder T and Tarran R and Tullis E	First clinical trials of novel ENaC targeting therapy, SPX-101, in healthy volunteers and adults with cystic fibrosis.
695082	Couroux P and Farias P and Rizvi L and Griffin K and Hudson C and Crowder T and Tarran R and Tullis E	First clinical trials of novel ENaC targeting therapy, SPX-101, in healthy volunteers and adults with cystic fibrosis.
695170	Cheng A and Hsieh SM and Pan SC and Li YH and Hsieh EF and Lee HC and Lin TW and Lai KL and Chen C and Shi-Chung Chang S and Chang SC	The safety and immunogenicity of a cell-derived adjuvanted H5N1 vaccine - A phase I randomized clinical trial.
695220	Small D and Ferguson-Sells L and Dahdah N and Bonnet D and Landry J and Li B	Pharmacokinetics and safety of tadalafil in a paediatric population with pulmonary arterial hypertension: A multiple ascending-dose study.
695231	Fediuk DJ and Matschke K and Liang Y and Pelletier KB and Wei H and Shi H and Bass A and Hickman A and Terra SG and Zhou S and Krishna R and Sahasrabudhe V	Bioequivalence of Ertugliflozin/Sitagliptin Fixed-Dose Combination Tablets and Coadministration of Respective Strengths of Individual Components.
695232	Fediuk DJ and Matschke K and Liang Y and Pelletier KB and Wei H and Shi H and Bass A and Hickman A and Terra SG and Zhou S and Krishna R and Sahasrabudhe V	Bioequivalence of Ertugliflozin/Sitagliptin Fixed-Dose Combination Tablets and Coadministration of Respective Strengths of Individual Components.
695233	Fediuk DJ and Matschke K and Liang Y and Pelletier KB and Wei H and Shi H and Bass A and Hickman A and Terra SG and Zhou S and Krishna R and Sahasrabudhe V	Bioequivalence of Ertugliflozin/Sitagliptin Fixed-Dose Combination Tablets and Coadministration of Respective Strengths of Individual Components.
695234	Fediuk DJ and Matschke K and Liang Y and Pelletier KB and Wei H and Shi H and Bass A and Hickman A and Terra SG and Zhou S and Krishna R and Sahasrabudhe V	Bioequivalence of Ertugliflozin/Sitagliptin Fixed-Dose Combination Tablets and Coadministration of Respective Strengths of Individual Components.
695361	McCrea JB and Macha S and Adedoyin A and Marshall W and Menzel K and Cho CR and Liu F and Zhao T and Levine V and Kraft WK and Yoon E and Panebianco D and Stoch SA and Iwamoto M	Pharmacokinetic Drug-Drug Interactions Between Letermovir and the Immunosuppressants Cyclosporine, Tacrolimus, Sirolimus, and Mycophenolate Mofetil.
695362	McCrea JB and Macha S and Adedoyin A and Marshall W and Menzel K and Cho CR and Liu F and Zhao T and Levine V and Kraft WK and Yoon E and Panebianco D and Stoch SA and Iwamoto M	Pharmacokinetic Drug-Drug Interactions Between Letermovir and the Immunosuppressants Cyclosporine, Tacrolimus, Sirolimus, and Mycophenolate Mofetil.
695363	McCrea JB and Macha S and Adedoyin A and Marshall W and Menzel K and Cho CR and Liu F and Zhao T and Levine V and Kraft WK and Yoon E and Panebianco D and Stoch SA and Iwamoto M	Pharmacokinetic Drug-Drug Interactions Between Letermovir and the Immunosuppressants Cyclosporine, Tacrolimus, Sirolimus, and Mycophenolate Mofetil.
695364	McCrea JB and Macha S and Adedoyin A and Marshall W and Menzel K and Cho CR and Liu F and Zhao T and Levine V and Kraft WK and Yoon E and Panebianco D and Stoch SA and Iwamoto M	Pharmacokinetic Drug-Drug Interactions Between Letermovir and the Immunosuppressants Cyclosporine, Tacrolimus, Sirolimus, and Mycophenolate Mofetil.

695365	McCrea JB and Macha S and Adedoyin A and Marshall W and Menzel K and Cho CR and Liu F and Zhao T and Levine V and Kraft WK and Yoon E and Panebianco D and Stoch SA and Iwamoto M	Pharmacokinetic Drug-Drug Interactions Between Letermovir and the Immunosuppressants Cyclosporine, Tacrolimus, Sirolimus, and Mycophenolate Mofetil.
695420	Muntoni F and Tejura B and Spinty S and Roper H and Hughes I and Layton G and Davies KE and Harriman S and Tinsley J	A Phase 1b Trial to Assess the Pharmacokinetics of Ezutromid in Pediatric Duchenne Muscular Dystrophy Patients on a Balanced Diet.
695440	Dungen HD and Kober L and Nodari S and Schou M and Otto C and Becka M and Kanefendt F and Winkelmann BR and Gislason G and Richard F and Nielsen OW and Gheorghiade M and Senni M	Safety and Tolerability of the Chymase Inhibitor Fulacimstat in Patients With Left Ventricular Dysfunction After Myocardial Infarction-Results of the CHIARA MIA 1 Trial.
695450	Thompson A and Lamberth E and Severs J and Scully I and Tarabar S and Ginis J and Jansen KU and Gruber WC and Scott DA and Watson W	Phase 1 trial of a 20-valent pneumococcal conjugate vaccine in healthy adults.
695460	Dejon-Agobe JC and Ateba-Ngoa U and Lalremruata A and Homoet A and Engelhorn J and Nouatin OP and Edoa JR and Fernandes JF and Esen M and Mouwenda YD and Betouke Ongwe EM and Massinga-Loembe M and Hoffman SL and Sim BKL and Theisen M and Kremsner PG and Adegnika AA and Lell B and MordmÃ¼ller B	Controlled Human Malaria Infection of Healthy Adults With Lifelong Malaria Exposure to Assess Safety, Immunogenicity, and Efficacy of the Asexual Blood Stage Malaria Vaccine Candidate GMZ2.
695480	Tylleskar I and Skulberg AK and Nilsen T and Skarra S and Dale O	Naloxone nasal spray - bioavailability and absorption pattern in a phase 1 study.
695500	Carter C and Houser KV and Yamshchikov GV and Bellamy AR and May J and Enama ME and Sarwar U and Larkin B and Bailer RT and Koup R and Chen GL and Patel SM and Winokur P and Belshe R and Dekker CL and Graham BS and Ledgerwood JE	Safety and immunogenicity of investigational seasonal influenza hemagglutinin DNA vaccine followed by trivalent inactivated vaccine administered intradermally or intramuscularly in healthy adults: An open-label randomized phase 1 clinical trial.
695580	Sneller MC and Clarridge KE and Seamon C and Shi V and Zorawski MD and Justement JS and Blazkova J and Huiting ED and Proschan MA and Mora JR and Shetzline M and Moir S and Lane HC and Chun TW and Fauci AS	An open-label phase 1 clinical trial of the anti-Î±(4)Î²(7) monoclonal antibody vedolizumab in HIV-infected individuals.
695750	Maguire AM and Russell S and Wellman JA and Chung DC and Yu ZF and Tillman A and Wittes J and Pappas J and Elci O and Marshall KA and McCague S and Reichert H and Davis M and Simonelli F and Leroy BP and Wright JF and High KA and Bennett J	Efficacy, Safety, and Durability of Voretigene Neparvovec-rzyl in RPE65 Mutation-Associated Inherited Retinal Dystrophy: Results of Phase 1 and 3 Trials.
695820	Modjarrad K and Roberts CC and Mills KT and Castellano AR and Paolino K and Muthumani K and Reuschel EL and Robb ML and Racine T and Oh MD and Lamarre C and Zaidi FI and Boyer J and Kudchodkar SB and Jeong M and Darden JM and Park YK and Scott PT and Remigio C and Parikh AP and Wise MC and Patel A and Duperret EK and Kim KY and Choi H and White S and Bagarazzi M and May JM and Kane D and Lee H and Kobinger G and Michael NL and Weiner DB and Thomas SJ and Maslow JN	Safety and immunogenicity of an anti-Middle East respiratory syndrome coronavirus DNA vaccine: a phase 1, open-label, single-arm, dose-escalation trial.

695841	Alexander VJ and Xia S and Hurh E and Hughes SG and O'Dea L and Geary RS and Witztum JL and Tsimikas S	N-acetyl galactosamine-conjugated antisense drug to APOC3 mRNA, triglycerides and atherogenic lipoprotein levels.
695842	Alexander VJ and Xia S and Hurh E and Hughes SG and O'Dea L and Geary RS and Witztum JL and Tsimikas S	N-acetyl galactosamine-conjugated antisense drug to APOC3 mRNA, triglycerides and atherogenic lipoprotein levels.
695890	Rouphael NG and Hurwitz SJ and Hart M and Beck A and Anderson EJ and Deye G and Osborn B and Cai SY and Focht C and Amegashie C and Bowlin TL and Brooks J and Mulligan MJ	Phase Ib Trial To Evaluate the Safety and Pharmacokinetics of Multiple Ascending Doses of Filociclovir (MBX-400, Cyclopropavir) in Healthy Volunteers.
695921	Eckburg PB and Lister T and Walpole S and Keutzer T and Utley L and Tomayko J and Kopp E and Farinola N and Coleman S	Safety, Tolerability, Pharmacokinetics, and Drug Interaction Potential of SPR741, an Intravenous Potentiator, after Single and Multiple Ascending Doses and When Combined with Î²-Lactam Antibiotics in Healthy Subjects.
695922	Eckburg PB and Lister T and Walpole S and Keutzer T and Utley L and Tomayko J and Kopp E and Farinola N and Coleman S	Safety, Tolerability, Pharmacokinetics, and Drug Interaction Potential of SPR741, an Intravenous Potentiator, after Single and Multiple Ascending Doses and When Combined with Î²-Lactam Antibiotics in Healthy Subjects.
695923	Eckburg PB and Lister T and Walpole S and Keutzer T and Utley L and Tomayko J and Kopp E and Farinola N and Coleman S	Safety, Tolerability, Pharmacokinetics, and Drug Interaction Potential of SPR741, an Intravenous Potentiator, after Single and Multiple Ascending Doses and When Combined with Î²-Lactam Antibiotics in Healthy Subjects.
695971	Dong R and Wang H and Li D and Lang L and Gray F and Liu Y and Laffont CM and Young M and Jiang J and Liu Z and Learned SM	Pharmacokinetics of Sublingual Buprenorphine Tablets Following Single and Multiple Doses in Chinese Participants With and Without Opioid Use Disorder.
695972	Dong R and Wang H and Li D and Lang L and Gray F and Liu Y and Laffont CM and Young M and Jiang J and Liu Z and Learned SM	Pharmacokinetics of Sublingual Buprenorphine Tablets Following Single and Multiple Doses in Chinese Participants With and Without Opioid Use Disorder.
696030	Rothenberg ME and Tagen M and Chang JH and Boyce-Rustay J and Friesenhahn M and Hackos DH and Hains A and Sutherlin D and Ward M and Cho W	Safety, Tolerability, and Pharmacokinetics of GDC-0276, a Novel Na(V)1.7 Inhibitor, in a First-in-Human, Single- and Multiple-Dose Study in Healthy Volunteers.
696100	Chattopadhyay N and Riecke K and Ligges S and Zimmermann T and Halabi A and Schultze-Mosgau MH	Effect of hepatic impairment on the pharmacokinetics of vilaprisan: An open-label, single-dose, parallel-group study.
696181	Bogman K and Brumm J and Hofmann C and Giraudon M and Niggli M and Sturm-Pellanda C and Sauter A and Sturm S and Mangold B and Schmitt C	Assessment of Drug-Drug Interactions between Taspoglutide, a Glucagon-Like Peptide-1 Agonist, and Drugs Commonly Used in Type 2 Diabetes Mellitus: Results of Five Phase I Trials.
696182	Bogman K and Brumm J and Hofmann C and Giraudon M and Niggli M and Sturm-Pellanda C and Sauter A and Sturm S and Mangold B and Schmitt C	Pharmacokinetics of Sublingual Buprenorphine Tablets Following Single and Multiple Doses in Chinese Participants With and Without Opioid Use Disorder.
696183	Bogman K and Brumm J and Hofmann C and Giraudon M and Niggli M and Sturm-Pellanda C and Sauter A and Sturm S and Mangold B and Schmitt C	Pharmacokinetics of Sublingual Buprenorphine Tablets Following Single and Multiple Doses in Chinese Participants With and Without Opioid Use Disorder.
696184	Bogman K and Brumm J and Hofmann C and Giraudon M and Niggli M and Sturm-Pellanda C and Sauter A and Sturm S and Mangold B and Schmitt C	Pharmacokinetics of Sublingual Buprenorphine Tablets Following Single and Multiple Doses in Chinese Participants With and Without Opioid Use Disorder.
696185	Bogman K and Brumm J and Hofmann C and Giraudon M and Niggli M and Sturm-Pellanda C and Sauter A and Sturm S and Mangold B and Schmitt C	Pharmacokinetics of Sublingual Buprenorphine Tablets Following Single and Multiple Doses in Chinese Participants With and Without Opioid Use Disorder.
696240	Prussick L and Rothstein B and Joshipura D and Saraiya A and Turkowski Y and Abdat R	Open-label, investigator-initiated, single-site exploratory trial evaluating secukinumab, an anti-interleukin-17A monoclonal

	and Alomran A and Zancanaro P and Kachuk C and Dumont N and Gottlieb AB and Rosmarin D	antibody, for patients with moderate-to-severe hidradenitis suppurativa.
696300	Queille-Roussel C and Nielsen J and Lacour JP	Vasoconstrictor potency of fixed-dose combination calcipotriol (50â€‰Î¼g/g) and betamethasone dipropionate (0.5â€‰mg/g) cutaneous foam versus other topical corticosteroids used to treat psoriasis vulgaris.
696410	Mallalieu NL and Wimalasundera S and Hsu JC and Douglass W and Wells C and Penades IC and Cuttica R and Huppertz HI and Joos R and Kimura Y and Milojevic D and Rosenkranz M and Schikler K and Constantin T and Wouters C	Intravenous dosing of tocilizumab in patients younger than two years of age with systemic juvenile idiopathic arthritis: results from an open-label phase 1 clinical trial.
696570	Dropulic LK and Oestreich MC and Pietz HL and Laing KJ and Hunsberger S and Lumbard K and Garabedian D and Turk SP and Chen A and Hornung RL and Seshadri C and Smith MT and Hosken NA and Phogat S and Chang LJ and Koelle DM and Wang K and Cohen JI	A Randomized, Double-Blinded, Placebo-Controlled, Phase 1 Study of a Replication-Defective Herpes Simplex Virus (HSV) Type 2 Vaccine, HSV529, in Adults With or Without HSV Infection.
696641	Ahmad Z and Banerjee P and Hamon S and Chan KC and Bouzelmat A and Sasiela WJ and Pordy R and Mellis S and Dansky H and Gipe DA and Dunbar RL	Inhibition of Angiopoietin-Like Protein 3 With a Monoclonal Antibody Reduces Triglycerides in Hypertriglyceridemia.
696642	Ahmad Z and Banerjee P and Hamon S and Chan KC and Bouzelmat A and Sasiela WJ and Pordy R and Mellis S and Dansky H and Gipe DA and Dunbar RL	Inhibition of Angiopoietin-Like Protein 3 With a Monoclonal Antibody Reduces Triglycerides in Hypertriglyceridemia.
696680	Heussler H and Cohen J and Silove N and Tich N and Bonn-Miller MO and Du W and O'Neill C and Sebree T	A phase 1/2, open-label assessment of the safety, tolerability, and efficacy of transdermal cannabidiol (ZYN002) for the treatment of pediatric fragile X syndrome.
696700	Enose-Akahata Y and Oh U and Ohayon J and Billioux BJ and Massoud R and Bryant BR and Vellucci A and Ngouth N and Cortese I and Waldmann TA and Jacobson S	Clinical trial of a humanized anti-IL-2/IL-15 receptor Î² chain in HAM/TSP.
696730	Keller MJ and Wood L and Billingsley JM and Ray LL and Goymer J and Sinclair S and McGinn AP and Marzinke MA and Frank B and Srinivasan S and Liu C and Atrio JM and Espinoza L and Mugo N and Spiegel HML and Anderson PL and Fredricks DN and Hendrix CW and Marrazzo J and Bosinger SE and Herold BC	Tenofovir disoproxil fumarate intravaginal ring for HIV pre-exposure prophylaxis in sexually active women: a phase 1, single-blind, randomised, controlled trial.
696760	Morrison EE and Oatey K and Gallagher B and Grahamslaw J and O'Brien R and Black P and Oosthuyzen W and Lee RJ and Weir CJ and Henriksen D and Dear JW	Principal results of a randomised open label exploratory, safety and tolerability study with calmangafodipir in patients treated with a 12â€¯h regimen of N-acetylcysteine for paracetamol overdose (POP trial).
696810	Heddle R and Smith A and Woodman R and Hissaria P and Petrovsky N	Randomized controlled trial demonstrating the benefits of delta inulin adjuvanted immunotherapy in patients with bee venom allergy.
696840	Tang W and Engman H and Zhu Y and Dayton B and Boulton DW	Bioequivalence and Food Effect of Dapagliflozin/Saxagliptin/Metformin Extended-release Fixed-combination Drug Products Compared With Coadministration of the Individual Components in Healthy Subjects.
696860	Bwakura Dangarembizi M and Samson P and Capparelli EV and Moore CB and Jean-Philippe P and Spector SA and Chakhtoura N and Benns A and Zimmer B	Establishing Dosing Recommendations for Efavirenz in HIV/TB-Coinfected Children Younger Than 3 Years.

	and Purdue L and Jackson C and Wallis C and Libous JL and Chadwick EG	
696901	Brys M and Fanning L and Hung S and Ellenbogen A and Penner N and Yang M and Welch M and Koenig E and David E and Fox T and Makh S and Aldred J and Goodman I and Pepinsky B and Liu Y and Graham D and Weihofen A and Cedarbaum JM	Randomized phase I clinical trial of anti-Î±-synuclein antibody BIIB054.
696902	Brys M and Fanning L and Hung S and Ellenbogen A and Penner N and Yang M and Welch M and Koenig E and David E and Fox T and Makh S and Aldred J and Goodman I and Pepinsky B and Liu Y and Graham D and Weihofen A and Cedarbaum JM	Randomized phase I clinical trial of anti-Î±-synuclein antibody BIIB054.
696970	Kosloski MP and Bow DAJ and Kikuchi R and Wang H and Kim EJ and Marsh K and Mensa F and Kort J and Liu W	Translation of In Vitro Transport Inhibition Studies to Clinical Drug-Drug Interactions for Glecaprevir and Pibrentasvir.
696990	Robertson SS and Mouksassi MS and Varin F	Population Pharmacokinetic/Pharmacodynamic Modeling of O-Desmethyltramadol in Young and Elderly Healthy Volunteers.
697120	Johnson VA and Cramer YS and Rosenkranz SL and Becker S and Klingman KL and Kallungal B and Coakley E and Acosta EP and Calandra G and Saag MS	Antiretroviral Activity of AMD11070 (An Orally Administered CXCR4 Entry Inhibitor): Results of NIH/NIAID AIDS Clinical Trials Group Protocol A5210.
697180	Iijima M and Orimo S and Terashi H and Suzuki M and Hayashi A and Shimura H and Mitoma H and Kitagawa K and Okuma Y	Efficacy of istradefylline for gait disorders with freezing of gait in Parkinson's disease: A single-arm, open-label, prospective, multicenter study.
697320	Taylor L and Crockett J and Tayo B and Morrison G	A Phase 1, Open-Label, Parallel-Group, Single-Dose Trial of the Pharmacokinetics and Safety of Cannabidiol (CBD) in Subjects With Mild to Severe Hepatic Impairment.
697351	Weiser T and Schepers C and MÃ¼ck T and Lange R	Pharmacokinetic Properties of Ibuprofen (IBU) From the Fixed-Dose Combination IBU/Caffeine (400/100Â mg; FDC) in Comparison With 400Â mg IBU as Acid or Lysinate Under Fasted and Fed Conditions-Data From 2 Single-Center, Single-Dose, Randomized Crossover Studies in Healthy Volunteers.
697352	Weiser T and Schepers C and MÃ¼ck T and Lange R	Pharmacokinetic Properties of Ibuprofen (IBU) From the Fixed-Dose Combination IBU/Caffeine (400/100Â mg; FDC) in Comparison With 400Â mg IBU as Acid or Lysinate Under Fasted and Fed Conditions-Data From 2 Single-Center, Single-Dose, Randomized Crossover Studies in Healthy Volunteers.
697390	Zomorodi K and Chen D and Lee L and Lasseter K and Marbury T	Single-Dose Pharmacokinetics and Safety of Solriamfetol in Participants With Normal or Impaired Renal Function and With End-Stage Renal Disease Requiring Hemodialysis.
697400	Kosloski MP and Zhao W and Li H and Pugatch D and Asatryan A and Kort J and Mensa FJ and Liu W	Drug-Drug Interactions of Tacrolimus or Cyclosporine With Glecaprevir and Pibrentasvir in Healthy Subjects.
697430	Munoz M and Olsen PS and Petersen TS and Manhart S and Waldorff S	Pharmacokinetics of ferric bepectate-a new intravenous iron drug for treating iron deficiency.
697441	Parnes JR and Sullivan JT and Chen L and Dias C	Pharmacokinetics, Safety, and Tolerability of Tezepelumab (AMG 157) in Healthy and Atopic Dermatitis Adult Subjects.
697442	Parnes JR and Sullivan JT and Chen L and Dias C	Pharmacokinetics, Safety, and Tolerability of Tezepelumab (AMG 157) in Healthy and Atopic Dermatitis Adult Subjects.
697520	Choi T and Komirenko AS and Riddle V and Kim A and Dhuria SV	No Effect of Plazomicin on the Pharmacokinetics of Metformin in Healthy Subjects.
697740	Tambyah PA and Oon J and Asli R and Kristanto W and Hwa SH and Vang F and Karwal L and Fuchs J and Santangelo JD and Gordon GS and Thomson C and Rao R and Dean H and Das SC and Stinchcomb DT	An inactivated enterovirus 71 vaccine is safe and immunogenic in healthy adults: A phase I, double blind, randomized, placebo-controlled, study of two dosages.

697750	Naggie S and Fierer DS and Hughes MD and Kim AY and Luetkemeyer A and Vu V and Roa J and Rwema S and Brainard DM and McHutchison JG and Peters MG and Kiser JJ and Marks KM and Chung RT	Ledipasvir/Sofosbuvir for 8 Weeks to Treat Acute Hepatitis C Virus Infections in Men With Human Immunodeficiency Virus Infections: Sofosbuvir-Containing Regimens Without Interferon for Treatment of Acute HCV in HIV-1 Infected Individuals.
697760	McCarthy JS and Smith B and Reid M and Berman J and Marquart L and Dobbin C and West L and Read LT and Dow GS	Blood Schizonticidal Activity and Safety of Tafenoquine When Administered as Chemoprophylaxis to Healthy, Nonimmune Participants Followed by Blood Stage Plasmodium falciparum Challenge: A Randomized, Double-blind, Placebo-controlled Phase 1b Study.
697820	Van Damme P and De Coster I and Bandyopadhyay AS and Revets H and Withanage K and De Smedt P and Suykens L and Oberste MS and Weldon WC and Costa-Clemens SA and Clemens R and Modlin J and Weiner AJ and Macadam AJ and Andino R and Kew OM and Konopka-Anstadt JL and Burns CC and Konz J and Wahid R and Gast C	The safety and immunogenicity of two novel live attenuated monovalent (serotype 2) oral poliovirus vaccines in healthy adults: a double-blind, single-centre phase 1 study.
697890	Woods CW and Sanchez AM and Swamy GK and McClain MT and Harrington L and Freeman D and Poore EA and Slifka DK and Poer DeRaad DE and Amanna IJ and Slifka MK and Cai S and Shahamatdar V and Wierzbicki MR and Amegashie C and Walter EB	An observer blinded, randomized, placebo-controlled, phase I dose escalation trial to evaluate the safety and immunogenicity of an inactivated West Nile virus Vaccine, HydroVax-001, in healthy adults.
697960	Katsube T and Saisho Y and Shimada J and Furuie H	Intrapulmonary pharmacokinetics of cefiderocol, a novel siderophore cephalosporin, in healthy adult subjects.
698240	Svecova D and Lubell MW and Casset-Semanaz F and Mackenzie H and Grenningloh R and Krueger JG	A randomized, double-blind, placebo-controlled phase 1 study of multiple ascending doses of subcutaneous M1095, an anti-interleukin 17A/F nanobody, in moderate-to-severe psoriasis.
698340	Meiffren G and Herbrand T and Anastassiadis E and Klein O and DeVries JH and Heise T and Alluis B and MÃ©gret C and Gaudier M and Soula O and Plum-MÃ¶rschel L	Better glycaemic control with BioChaperone glargine lispro co-formulation than with insulin lispro Mix25 or separate glargine and lispro administrations after a test meal in people with type 2 diabetes.
698380	Li Y and Zhan H and Fan Y and Zhang J and Cao G and Yu J and Chen Y and Guo B	Determination of DP-VPA and its active metabolite, VPA, in human plasma, urine, and feces by UPLC-MS/MS: A clinical pharmacokinetics and excretion study.
698400	Parasrampuria R and Ford SL and Lou Y and Fu C and Bakshi KK and Tenorio AR and Trezza C and Spreen WR and Patel P	A Phase I Study to Evaluate the Pharmacokinetics and Safety of Cabotegravir in Adults With Severe Renal Impairment and Healthy Matched Control Participants.
698410	Anderson K and Zheng H and Kotecha M and Cuvin J and Scott B and Sharma S and Qin AR and Namour F and Xin Y	The Relative Bioavailability and Effects of Food and Acid-Reducing Agents on Filgotinib Tablets in Healthy Subjects.
698420	Shen Z and Lee CA and Wallach K and Valdez S and Wilson DM and Kerr B and Gillen M	Lesinurad: Evaluation of Pharmacokinetic and Pharmacodynamic Interactions With Warfarin in Healthy Volunteers.
698490	Lobo RA and Liu J and Stanczyk FZ and Constantine GD and Pickar JH and Shadiack AM and Bernick B and Mirkin S	Estradiol and progesterone bioavailability for moderate to severe vasomotor symptom treatment and endometrial protection with the continuous-combined regimen of TX-001HR (oral estradiol and progesterone capsules).
698510	Ino H and Doi Y and Liefaard L and Cookson L and Chen C and Itoh H and Igarashi H and Nakano A	Evaluation of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of a Single Intravenous Dose of Miridesap in Healthy Japanese Subjects.
698600	Tortorici MA and Duffy D and Evans R and Feaster J and Gille A and Mant TGK and Wright SD and D'Andrea D	Pharmacokinetics and Safety of CSL112 (Apolipoprotein A-I [Human]) in Adults With Moderate Renal Impairment and Normal Renal Function.

698760	Anywaine Z and Whitworth H and Kaleebu P and Praygod G and Shukarev G and Manno D and Kapiga S and Grosskurth H and Kalluvya S and Bockstal V and Anumendem D and Luhn K and Robinson C and Douoguih M and Watson-Jones D	Safety and Immunogenicity of a 2-Dose Heterologous Vaccination Regimen With Ad26.ZEBOV and MVA-BN-Filo Ebola Vaccines: 12-Month Data From a Phase 1 Randomized Clinical Trial in Uganda and Tanzania.
698770	Mutua G and Anzala O and Luhn K and Robinson C and Bockstal V and Anumendem D and Douoguih M	Safety and Immunogenicity of a 2-Dose Heterologous Vaccine Regimen With Ad26.ZEBOV and MVA-BN-Filo Ebola Vaccines: 12-Month Data From a Phase 1 Randomized Clinical Trial in Nairobi, Kenya.
698840	Mealy MA and Levy M	A pilot safety study of ublituximab, a monoclonal antibody against CD20, in acute relapses of neuromyelitis optica spectrum disorder.
698881	Wu J and Wu H and Wang Y and Chen Y and Guo B and Cao G and Wu X and Yu J and Wu J and Zhu D and Guo Y and Yuan H and Hu F and Zhang J	Tolerability and Pharmacokinetics of Contezolid at Therapeutic and Supratherapeutic Doses in Healthy Chinese Subjects, and Assessment of Contezolid Dosing Regimens Based on Pharmacokinetic/Pharmacodynamic Analysis.
698882	Wu J and Wu H and Wang Y and Chen Y and Guo B and Cao G and Wu X and Yu J and Wu J and Zhu D and Guo Y and Yuan H and Hu F and Zhang J	Tolerability and Pharmacokinetics of Contezolid at Therapeutic and Supratherapeutic Doses in Healthy Chinese Subjects, and Assessment of Contezolid Dosing Regimens Based on Pharmacokinetic/Pharmacodynamic Analysis.
698890	Boxer AL and Qureshi I and Ahlijanian M and Grundman M and Golbe LI and Litvan I and Honig LS and Tuite P and McFarland NR and O'Suilleabhain P and Xie T and Tirucherai GS and Bechtold C and Bordelon Y and Geldmacher DS and Grossman M and Isaacson S and Zesiewicz T and Olsson T and Muralidharan KK and Graham DL and O'Gorman J and Haeberlein SB and Dam T	Safety of the tau-directed monoclonal antibody BIIB092 in progressive supranuclear palsy: a randomised, placebo-controlled, multiple ascending dose phase 1b trial.
698920	Okour M and Puri A and Chen G and Port K and Berni A and Khindri S and Schneider I and Tenero D	A Phase I Study to Show the Relative Bioavailability and Bioequivalence of Fixed-Dose Combinations of Ambrisentan and Tadalafil in Healthy Subjects.
698930	Wheless JW and Dlugos D and Miller I and Oh DA and Parikh N and Phillips S and Renfroe JB and Roberts CM and Saeed I and Sparagana SP and Yu J and Cilio MR	Pharmacokinetics and Tolerability of Multiple Doses of Pharmaceutical-Grade Synthetic Cannabidiol in Pediatric Patients with Treatment-Resistant Epilepsy.
698961	Xu HR and Zhang JW and Chen WL and Ning ZQ and Li XN	Pharmacokinetics, Safety and Tolerability of Chiglitazar, A Novel Peroxisome Proliferator-Activated Receptor (PPAR) Pan-Agonist, in HealthyÂ Chinese Volunteers:Â A Phase I Study.
698962	Xu HR and Zhang JW and Chen WL and Ning ZQ and Li XN	Pharmacokinetics, Safety and Tolerability of Chiglitazar, A Novel Peroxisome Proliferator-Activated Receptor (PPAR) Pan-Agonist, in HealthyÂ Chinese Volunteers:Â A Phase I Study.
698963	Xu HR and Zhang JW and Chen WL and Ning ZQ and Li XN	Pharmacokinetics, Safety and Tolerability of Chiglitazar, A Novel Peroxisome Proliferator-Activated Receptor (PPAR) Pan-Agonist, in HealthyÂ Chinese Volunteers:Â A Phase I Study.
699011	Dennie L	Safety and Efficacy of 0.5% Carbomer 980 Gel for Treatment of Symptoms of Common Cold: Results of 2 Randomized Trials.
699012	Dennie L	Safety and Efficacy of 0.5% Carbomer 980 Gel for Treatment of Symptoms of Common Cold: Results of 2 Randomized Trials.
699020	Nazeri S and Jamshidi AR and Mahmoudi M and Vojdanian M and Khadem Azarian S and Afraei S and Mostafaei S and Hosseini M and Mirshafiey A	The safety and efficacy of Guluronic acid (G2013) in ankylosing spondylitis: A randomized controlled parallel clinical trial.
699070	Peck M and Rothenberg ME and Deng R and Lewin-Koh N and She G and Kamath AV and Carrasco-Triguero M and Saad O and Castro A and Teufel L and Dickerson DS and Leonardelli M and Tavel JA	A Phase 1, Randomized, Single-Ascending-Dose Study To Investigate the Safety, Tolerability, and Pharmacokinetics of DSTA4637S, an Anti-Staphylococcus aureus Thiomab Antibody-Antibiotic Conjugate, in Healthy Volunteers.

699120	Stass H and Nagelschmitz J and Kappeler D and Sommerer K and Patzlaff A and Weimann B	Ciprofloxacin Dry Powder for Inhalation: Inspiratory Flow in Patients with Non-cystic Fibrosis Bronchiectasis.
699140	Cerrone M and Alfarisi O and Neary M and Marzinke MA and Parsons TL and Owen A and Maartens G and Pozniak A and Flexner C and Boffito M	Rifampicin effect on intracellular and plasma pharmacokinetics of tenofovir alafenamide.
699421	Ikeda S and Takano Y and Schwab D and Portron A and Kasahara-Ito N and Saito T and Iida S	Effect of Renal Impairment on the Pharmacokinetics and Pharmacodynamics of Tofogliflozin (A SELECTIVE SGLT2 Inhibitor) in Patients with Type 2 Diabetes Mellitus.
699422	Ikeda S and Takano Y and Schwab D and Portron A and Kasahara-Ito N and Saito T and Iida S	Effect of Renal Impairment on the Pharmacokinetics and Pharmacodynamics of Tofogliflozin (A SELECTIVE SGLT2 Inhibitor) in Patients with Type 2 Diabetes Mellitus.
699441	Feldman RA and Fuhr R and Smolenov I and Mick Ribeiro A and Panther L and Watson M and Senn JJ and Smith M and Almarsson Ó¦ and Pujar HS and Laska ME and Thompson J and Zaks T and Ciaramella G	mRNA vaccines against H10N8 and H7N9 influenza viruses of pandemic potential are immunogenic and well tolerated in healthy adults in phase 1 randomized clinical trials.
699442	Feldman RA and Fuhr R and Smolenov I and Mick Ribeiro A and Panther L and Watson M and Senn JJ and Smith M and Almarsson Ó¦ and Pujar HS and Laska ME and Thompson J and Zaks T and Ciaramella G	mRNA vaccines against H10N8 and H7N9 influenza viruses of pandemic potential are immunogenic and well tolerated in healthy adults in phase 1 randomized clinical trials.
699490	Van Damme P and Leroux-Roels G and Vandermeulen C and De Ryck I and Tasciotti A and Dozot M and Moraschini L and Testa M and Arora AK	Safety and immunogenicity of non-typeable Haemophilus influenzae-Moraxella catarrhalis vaccine.
699500	Darras BT and Chiriboga CA and Iannaccone ST and Swoboda KJ and Montes J and Mignon L and Xia S and Bennett CF and Bishop KM and Shefner JM and Green AM and Sun P and Bhan I and Gheuens S and Schneider E and Farwell W and De Vivo DC	Nusinersen in later-onset spinal muscular atrophy: Long-term results from the phase 1/2 studies.
699580	Bhatt DL and Pollack CV and Weitz JI and Jennings LK and Xu S and Arnold SE and Umstead BR and Mays MC and Lee JS	Antibody-Based Ticagrelor Reversal Agent in Healthy Volunteers.
699610	Leroux-Roels G and De Boever F and Maes C and Nguyen TL and Baker S and Gonzalez Lopez A	Safety and immunogenicity of a respiratory syncytial virus fusion glycoprotein F subunit vaccine in healthy adults: Results of a phase 1, randomized, observer-blind, controlled, dosage-escalation study.
699700	O'Neill BV and Dodds CM and Miller SR and Gupta A and Lawrence P and Bullman J and Chen C and Dewit O and Kumar S and Dustagheer M and Price J and Shabbir S and Nathan PJ	The effects of GSK2981710, a medium-chain triglyceride, on cognitive function in healthy older participants: A randomised, placebo-controlled study.
699740	Voors-Pette C and Lebozec K and Dogterom P and Jullien L and Billiald P and Ferlan P and Renaud L and Favre-Bulle O and Avenard G and Machacek M and PlÃ©tan Y and Jandrot-Perrus M	Safety and Tolerability, Pharmacokinetics, and Pharmacodynamics of ACT017, an Antiplatelet GPVI (Glycoprotein VI) Fab.
699770	Richard M and Kaufmann P and Kornberger R and Dingemanse J	First-in-man study of ACT-709478, a novel selective triple T-type calcium channel blocker.
699800	Chen Q and Hu C and Yu H and Shen K and Assam PN and Gillen M and Liu Y and Dorinsky P	Pharmacokinetics and Tolerability of Budesonide/Glycopyrronium/Formoterol Fumarate Dihydrate and Glycopyrronium/Formoterol Fumarate Dihydrate Metered Dose Inhalers in Healthy Chinese Adults: A Randomized, Double-blind, Parallel-group Study.
699851	Bernstein G and Davis K and Mills C and Wang L and McDonnell M and Oldenhof J	Characterization of the Safety and Pharmacokinetic Profile of D-Methadone, a Novel N-Methyl-D-Aspartate Receptor

	and Inturrisi C and Manfredi PL and Vitolo OV	Antagonist in Healthy, Opioid-Naive Subjects: Results of Two Phase 1 Studies.
699852	Bernstein G and Davis K and Mills C and Wang L and McDonnell M and Oldenhof J and Inturrisi C and Manfredi PL and Vitolo OV	Characterization of the Safety and Pharmacokinetic Profile of D-Methadone, a Novel N-Methyl-D-Aspartate Receptor Antagonist in Healthy, Opioid-Naive Subjects: Results of Two Phase 1 Studies.
699860	Finnema SJ and Rossano S and Naganawa M and Henry S and Gao H and Pracitto R and Maguire RP and Mercier J and Kervyn S and Nicolas JM and Klitgaard H and DeBruyn S and Otoul C and Martin P and Muglia P and Matuskey D and Nabulsi NB and Huang Y and Kaminski RM and Hannestad J and Stockis A and Carson RE	A single-center, open-label positron emission tomography study to evaluate brivaracetam and levetiracetam synaptic vesicle glycoprotein 2A binding in healthy volunteers.
699870	Sun L and McDonnell D and Liu J and von Moltke L	Effect of Food on the Pharmacokinetics of a Combination of Olanzapine and Samidorphan.
699900	Sun L and McDonnell D and Yu M and Kumar V and von Moltke L	A Phase I Open-Label Study to Evaluate the Effects of Rifampin on the Pharmacokinetics of Olanzapine and Samidorphan Administered in Combination in Healthy Human Subjects.
699980	Overcash JS and Bhiwandi P and Garrity-Ryan L and Steenbergen J and Bai S and Chitra S and Manley A and Tzanis E	Pharmacokinetics, Safety, and Clinical Outcomes of Omadacycline in Women with Cystitis: Results from a Phase 1b Study.
699990	GonÃ§alves E and Bonduelle O and Soria A and Loulergue P and Rousseau A and Cachanado M and Bonnabau H and Thiebaut R and Tchitchek N and Behillil S and van der Werf S and Vogt A and Simon T and Launay O and CombadiÃ¨re B	Innate gene signature distinguishes humoral versus cytotoxic responses to influenza vaccination.
700000	Schiffmann R and Goker-Alpan O and Holida M and Giraldo P and Barisoni L and Colvin RB and Jennette CJ and Maegawa G and Boyadjiev SA and Gonzalez D and Nicholls K and Tuffaha A and Atta MG and Rup B and Charney MR and Paz A and Szlaifer M and Alon S and Brill-Almon E and Chertkoff R and Hughes D	Pegunigalsidase alfa, a novel PEGylated enzyme replacement therapy for Fabry disease, provides sustained plasma concentrations and favorable pharmacodynamics: A 1-year Phase 1/2 clinical trial.
700031	Wrishko RE and McCrea JB and Yee KL and Liu W and Panebianco D and Mangin E and Chakravarthy M and Martinez-Cantarin MP and Kraft WK	Effect of CYP3A Inhibition and Induction on the Pharmacokinetics of Suvorexant: Two Phase I, Open-Label, Fixed-Sequence Trials in Healthy Subjects.
700032	Wrishko RE and McCrea JB and Yee KL and Liu W and Panebianco D and Mangin E and Chakravarthy M and Martinez-Cantarin MP and Kraft WK	Effect of CYP3A Inhibition and Induction on the Pharmacokinetics of Suvorexant: Two Phase I, Open-Label, Fixed-Sequence Trials in Healthy Subjects.
700110	Hennermann JB and Arash-Kaps L and Fekete G and Schaaf A and Busch A and Frischmuth T	Pharmacokinetics, pharmacodynamics, and safety of moss-aGalactosidase A in patients with Fabry disease.
700130	Green CA and Sande CJ and Scarselli E and Capone S and Vitelli A and Nicosia A and Silva-Reyes L and Thompson AJ and de Lara CM and Taylor KS and Haworth K and Hutchings CL and Cargill T and Angus B and Klenerman P and Pollard AJ	Novel genetically-modified chimpanzee adenovirus and MVA-vectored respiratory syncytial virus vaccine safely boosts humoral and cellular immunity in healthy older adults.
700170	Baakman AC and Zuiker R and van Gerven JMA and Gross N and Yang R and Fetell M and Gershon A and Gilgun-Sherki Y and Hellriegel E and Spiegelstein O	Central nervous system effects of the histamine-3 receptor antagonist CEP-26401, in comparison with modafinil and donepezil, after a single dose in a cross-over study in healthy volunteers.

700190	Cowart D and Venuti RP and Lynch K and Guptill JT and Noveck RJ and Foo SY	A Phase 1 Randomized Study of Single Intravenous Infusions of the Novel Nitroxyl Donor BMS-986231 in Healthy Volunteers.
700200	Garg V and Shen J and Li C and Agarwal S and Gebre A and Robertson S and Huang J and Han L and Jiang L and Stephan K and Wang LT and Lekstrom-Himes J	Pharmacokinetic and Drug-Drug Interaction Profiles of the Combination of Tezacaftor/Ivacaftor.
700200	Garg V and Shen J and Li C and Agarwal S and Gebre A and Robertson S and Huang J and Han L and Jiang L and Stephan K and Wang LT and Lekstrom-Himes J	Pharmacokinetic and Drug-Drug Interaction Profiles of the Combination of Tezacaftor/Ivacaftor.
700200	Garg V and Shen J and Li C and Agarwal S and Gebre A and Robertson S and Huang J and Han L and Jiang L and Stephan K and Wang LT and Lekstrom-Himes J	Pharmacokinetic and Drug-Drug Interaction Profiles of the Combination of Tezacaftor/Ivacaftor.
700220	Stass H and Lettieri J and Vanevski KM and Willmann S and James LP and Sullivan JE and Arrieta AC and Bradley JS	Pharmacokinetics, Safety, and Tolerability of Single-Dose Intravenous Moxifloxacin in Pediatric Patients: Dose Optimization in a Phase 1 Study.
700241	Sheetz M and Barrington P and Callies S and Berg PH and McColm J and Marbury T and Decker B and Dyas GL and Truhlar SME and Benschop R and Leung D and Berg J and Witcher DR	Targeting the hepcidin-ferroportin pathway in anaemia of chronic kidney disease.
700242	Sheetz M and Barrington P and Callies S and Berg PH and McColm J and Marbury T and Decker B and Dyas GL and Truhlar SME and Benschop R and Leung D and Berg J and Witcher DR	Targeting the hepcidin-ferroportin pathway in anaemia of chronic kidney disease.
700243	Sheetz M and Barrington P and Callies S and Berg PH and McColm J and Marbury T and Decker B and Dyas GL and Truhlar SME and Benschop R and Leung D and Berg J and Witcher DR	Targeting the hepcidin-ferroportin pathway in anaemia of chronic kidney disease.
700244	Sheetz M and Barrington P and Callies S and Berg PH and McColm J and Marbury T and Decker B and Dyas GL and Truhlar SME and Benschop R and Leung D and Berg J and Witcher DR	Targeting the hepcidin-ferroportin pathway in anaemia of chronic kidney disease.
700370	Khedkar A and Lebovitz H and Fleming A and Cherrington A and Jose V and Athalye SN and Vishweswaramurthy A	Impact of Insulin Tregopil and Its Permeation Enhancer on Pharmacokinetics of Metformin in Healthy Volunteers: Randomized, Open-Label, Placebo-Controlled, Crossover Study.
700420	Brown K and Thomas D and McKenney K and Reeder M and Simonson RB and Bicer C and Nettles RE and Crauwels H	Impact of Splitting or Crushing on the Relative Bioavailability of the Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Single-Tablet Regimen.
700490	Yamada H and Yonemura T and Nemoto T and Ninomiya N and Irie S	Pharmacokinetics of Tenofovir Alafenamide, Tenofovir, and Emtricitabine Following Administration of Coformulated Emtricitabine/Tenofovir Alafenamide in Healthy Japanese Subjects.
700540	Ali SO and Yu XQ and Robbie GJ and Wu Y and Shoemaker K and Yu L and DiGiandomenico A and Keller AE and Anude C and Hernandez-Illas M and Bellamy T and Falloon J and Dubovsky F and Jafri HS	Phase 1 study of MEDI3902, an investigational anti-Pseudomonas aeruginosa PcrV and Psl bispecific human monoclonal antibody, in healthy adults.
700550	Sun L and McDonnell D and Liu J and von Moltke L	Bioequivalence of Olanzapine Given in Combination With Samidorphan as a Bilayer Tablet (ALKS 3831) Compared With Olanzapine-Alone Tablets: Results From a Randomized, Crossover Relative Bioavailability Study.

700561	Kanefendt F and ThuÃŸ U and Becka M and Boxnick S and Berse M and Schultz A and Otto C	Pharmacokinetics, Safety, and Tolerability of the Novel Chymase Inhibitor BAY 1142524 in Healthy Male Volunteers.
700562	Kanefendt F and ThuÃŸ U and Becka M and Boxnick S and Berse M and Schultz A and Otto C	Pharmacokinetics, Safety, and Tolerability of the Novel Chymase Inhibitor BAY 1142524 in Healthy Male Volunteers.
700563	Kanefendt F and ThuÃŸ U and Becka M and Boxnick S and Berse M and Schultz A and Otto C	Pharmacokinetics, Safety, and Tolerability of the Novel Chymase Inhibitor BAY 1142524 in Healthy Male Volunteers.
700590	Andersson KE and Longstreth J and Brucker BM and Campeau L and Cheng L and Francis L and Fein S	Pharmacokinetic and Pharmacodynamic Properties of a Micro-Dose Nasal Spray Formulation of Desmopressin (AV002) in Healthy Water-Loaded Subjects.
700610	Howard J and Hemmaway CJ and Telfer P and Layton DM and Porter J and Awogbade M and Mant T and Gretler DD and Dufu K and Hutchaleelaha A and Patel M and Siu V and Dixon S and Landsman N and Tonda M and Lehrer-Graiwer J	A phase 1/2 ascending dose study and open-label extension study of voxelotor in patients with sickle cell disease.
700731	Venkatraman N and Ndiaye BP and Bowyer G and Wade D and Sridhar S and Wright D and Powlson J and Ndiaye I and DiÃ¨ye S and Thompson C and Bakhoum M and Morter R and Capone S and Del Sorbo M and Jamieson S and Rampling T and Datoo M and Roberts R and Poulton I and Griffiths O and Ballou WR and Roman F and Lewis DJM and Lawrie A and Imoukhuede E and Gilbert SC and Dieye TN and Ewer KJ and Mboup S and Hill AVS	Safety and Immunogenicity of a Heterologous Prime-Boost Ebola Virus Vaccine Regimen in Healthy Adults in the United Kingdom and Senegal.
700732	Venkatraman N and Ndiaye BP and Bowyer G and Wade D and Sridhar S and Wright D and Powlson J and Ndiaye I and DiÃ¨ye S and Thompson C and Bakhoum M and Morter R and Capone S and Del Sorbo M and Jamieson S and Rampling T and Datoo M and Roberts R and Poulton I and Griffiths O and Ballou WR and Roman F and Lewis DJM and Lawrie A and Imoukhuede E and Gilbert SC and Dieye TN and Ewer KJ and Mboup S and Hill AVS	Safety and Immunogenicity of a Heterologous Prime-Boost Ebola Virus Vaccine Regimen in Healthy Adults in the United Kingdom and Senegal.
700733	Venkatraman N and Ndiaye BP and Bowyer G and Wade D and Sridhar S and Wright D and Powlson J and Ndiaye I and DiÃ¨ye S and Thompson C and Bakhoum M and Morter R and Capone S and Del Sorbo M and Jamieson S and Rampling T and Datoo M and Roberts R and Poulton I and Griffiths O and Ballou WR and Roman F and Lewis DJM and Lawrie A and Imoukhuede E and Gilbert SC and Dieye TN and Ewer KJ and Mboup S and Hill AVS	Safety and Immunogenicity of a Heterologous Prime-Boost Ebola Virus Vaccine Regimen in Healthy Adults in the United Kingdom and Senegal.
700781	Wicha WW and Prince WT and Lell C and Heilmayer W and Gelone SP	Pharmacokinetics and tolerability of lefamulin following intravenous and oral dosing.
700782	Wicha WW and Prince WT and Lell C and Heilmayer W and Gelone SP	Pharmacokinetics and tolerability of lefamulin following intravenous and oral dosing.
700783	Wicha WW and Prince WT and Lell C and Heilmayer W and Gelone SP	Pharmacokinetics and tolerability of lefamulin following intravenous and oral dosing.

700801	Smith N and Longo N and Levert K and Hyland K and Blau N	Phase I clinical evaluation of CNSA-001 (sepiapterin), a novel pharmacological treatment for phenylketonuria and tetrahydrobiopterin deficiencies, in healthy volunteers.
700802	Smith N and Longo N and Levert K and Hyland K and Blau N	Phase I clinical evaluation of CNSA-001 (sepiapterin), a novel pharmacological treatment for phenylketonuria and tetrahydrobiopterin deficiencies, in healthy volunteers.
700820	Priddy FH and Lewis DJM and Gelderblom HC and Hassanin H and Streatfield C and LaBranche C and Hare J and Cox JH and Dally L and Bendel D and Montefiori D and Sayeed E and Ackland J and Gilmour J and Schnepp BC and Wright JF and Johnson P	Adeno-associated virus vectored immunoprophylaxis to prevent HIV in healthy adults: a phase 1 randomised controlled trial.
700870	Collins KA and RÃ¼ckle T and Elliott S and Marquart L and Ballard E and Chalon S and Griffin P and MÃ¶hrle JJ and McCarthy JS	DSM265 at 400 Milligrams Clears Asexual Stage Parasites but Not Mature Gametocytes from the Blood of Healthy Subjects Experimentally Infected with Plasmodium falciparum.
700910	Wahid R and Kotloff KL and Levine MM and Sztein MB	Cell mediated immune responses elicited in volunteers following immunization with candidate live oral Salmonella enterica serovar Paratyphi A attenuated vaccine strain CVD 1902.
700941	Liu T and Gobburu JVS and Po MD and McLean A and DeSousa NJ and Sallee FR and Incledon B	Pharmacokinetics of HLD200, a Delayed-Release and Extended-Release Methylphenidate: Evaluation of Dose Proportionality, Food Effect, Multiple-Dose Modeling, and Comparative Bioavailability with Immediate-Release Methylphenidate in Healthy Adults.
700942	Liu T and Gobburu JVS and Po MD and McLean A and DeSousa NJ and Sallee FR and Incledon B	Pharmacokinetics of HLD200, a Delayed-Release and Extended-Release Methylphenidate: Evaluation of Dose Proportionality, Food Effect, Multiple-Dose Modeling, and Comparative Bioavailability with Immediate-Release Methylphenidate in Healthy Adults.
700943	Liu T and Gobburu JVS and Po MD and McLean A and DeSousa NJ and Sallee FR and Incledon B	Pharmacokinetics of HLD200, a Delayed-Release and Extended-Release Methylphenidate: Evaluation of Dose Proportionality, Food Effect, Multiple-Dose Modeling, and Comparative Bioavailability with Immediate-Release Methylphenidate in Healthy Adults.
700961	Tamaki S and Shibata T and Hunt T and Gerhardt B and Yamada H and Pai SM	Pharmacokinetics, Food Effect, Ketoconazole Interaction, and Safety of JTK-853, a Novel Nonnucleoside HCV Polymerase Inhibitor, After Ascending Single and Multiple Doses in Healthy Subjects.
700962	Tamaki S and Shibata T and Hunt T and Gerhardt B and Yamada H and Pai SM	Pharmacokinetics, Food Effect, Ketoconazole Interaction, and Safety of JTK-853, a Novel Nonnucleoside HCV Polymerase Inhibitor, After Ascending Single and Multiple Doses in Healthy Subjects.
701010	An G and Murry DJ and Gajurel K and Bach T and Deye G and Stebounova LV and Codd EE and Horton J and Gonzalez AE and Garcia HH and Ince D and Hodgson-Zingman D and Nomicos EYH and Conrad T and Kennedy J and Jones W and Gilman RH and Winokur P	Pharmacokinetics, Safety, and Tolerability of Oxfendazole in Healthy Volunteers: a Randomized, Placebo-Controlled First-in-Human Single-Dose Escalation Study.
701100	Mack CL and Spino C and Alonso EM and Bezerra JA and Moore J and Goodhue C and Ng VL and Karpen SJ and Venkat V and Loomes KM and Wang K and Sherker AH and Magee JC and Sokol RJ	A Phase I/IIa Trial of Intravenous Immunoglobulin Following Portoenterostomy in Biliary Atresia.
701131	Brigandi RA and Zhu J and Murnane AA and Reedy BA and Shakib S	A Phase 1 Randomized, Placebo-Controlled Trial With a Topical Inhibitor of Stearoyl-Coenzyme A Desaturase 1 Under Occluded and Nonoccluded Conditions.
701132	Brigandi RA and Zhu J and Murnane AA and Reedy BA and Shakib S	A Phase 1 Randomized, Placebo-Controlled Trial With a Topical Inhibitor of Stearoyl-Coenzyme A Desaturase 1 Under Occluded and Nonoccluded Conditions.

701180	Salcedo C and Joubert PH and Ferrer MD and Canals AZ and Maduell F and Torregrosa V and Campistol JM and Ojeda R and PerellÃ³ J	A phase 1b randomized, placebo-controlled clinical trial with SNF472 in haemodialysis patients.
701190	Yuen MF and Gane EJ and Kim DJ and Weilert F and Yuen Chan HL and Lalezari J and Hwang SG and Nguyen T and Flores O and Hartman G and Liaw S and Lenz O and Kakuda TN and Talloen W and Schwabe C and Klumpp K and Brown N	Antiviral Activity, Safety, and Pharmacokinetics of Capsid Assembly Modulator NVR 3-778 in Patients with Chronic HBV Infection.
701210	Gan LM and LagerstrÃ¶m-FermÃ©r M and Ericsson H and Nelander K and Lindstedt EL and MichaÃ«lsson E and Kjaer M and Heijer M and Whatling C and Fuhr R	Safety, tolerability, pharmacokinetics and effect on serum uric acid of the myeloperoxidase inhibitor AZD4831 in a randomized, placebo-controlled, phase I study in healthy volunteers.
701511	Shibata T and Nomura Y and Takada A and Ueno M and Katashima M and Yazawa R and Furihata K	Evaluation of Food and Spherical Carbon Adsorbent Effects on the Pharmacokinetics of Roxadustat in Healthy Nonelderly Adult Male Japanese Subjects.
701512	Shibata T and Nomura Y and Takada A and Ueno M and Katashima M and Yazawa R and Furihata K	Evaluation of Food and Spherical Carbon Adsorbent Effects on the Pharmacokinetics of Roxadustat in Healthy Nonelderly Adult Male Japanese Subjects.
701541	Luke DR and Lee KKY and Rausch CW and Cheng C	Phase 1 Study of the Pharmacology of BTI320 Before High-Glycemic Meals.
701542	Luke DR and Lee KKY and Rausch CW and Cheng C	Phase 1 Study of the Pharmacology of BTI320 Before High-Glycemic Meals.
701551	Dawra VK and Cutler DL and Zhou S and Krishna R and Shi H and Liang Y and Alvey C and Hickman A and Saur D and Terra SG and Sahasrabudhe V	Assessment of the Drug Interaction Potential of Ertugliflozin With Sitagliptin, Metformin, Glimepiride, or Simvastatin in Healthy Subjects.
701552	Dawra VK and Cutler DL and Zhou S and Krishna R and Shi H and Liang Y and Alvey C and Hickman A and Saur D and Terra SG and Sahasrabudhe V	Assessment of the Drug Interaction Potential of Ertugliflozin With Sitagliptin, Metformin, Glimepiride, or Simvastatin in Healthy Subjects.
701553	Dawra VK and Cutler DL and Zhou S and Krishna R and Shi H and Liang Y and Alvey C and Hickman A and Saur D and Terra SG and Sahasrabudhe V	Assessment of the Drug Interaction Potential of Ertugliflozin With Sitagliptin, Metformin, Glimepiride, or Simvastatin in Healthy Subjects.
701554	Dawra VK and Cutler DL and Zhou S and Krishna R and Shi H and Liang Y and Alvey C and Hickman A and Saur D and Terra SG and Sahasrabudhe V	Assessment of the Drug Interaction Potential of Ertugliflozin With Sitagliptin, Metformin, Glimepiride, or Simvastatin in Healthy Subjects.
701600	Pan SC and Hsieh SM and Lin CF and Hsu YS and Chang M and Chang SC	A randomized, double-blind, controlled clinical trial to evaluate the safety and immunogenicity of an intranasally administered trivalent inactivated influenza vaccine with adjuvant LTh(Î±K): A phase I study.
701620	Arrieta AC and Sung L and Bradley JS and Zwaan CM and Gates D and Waskin H and Carmelitano P and Groll AH and Lehrnbecher T and Mangin E and Joshi A and Kartsonis NA and Walsh TJ and Paschke A	A non-randomized trial to assess the safety, tolerability, and pharmacokinetics of posaconazole oral suspension in immunocompromised children with neutropenia.
701631	Doener F and Hong HS and Meyer I and Tadjalli-Mehr K and Daehling A and Heidenreich R and Koch SD and Fotin-Mleczek M and Gnad-Vogt U	RNA-based adjuvant CV8102 enhances the immunogenicity of a licensed rabies vaccine in a first-in-human trial.
701632	Doener F and Hong HS and Meyer I and Tadjalli-Mehr K and Daehling A and Heidenreich R and Koch SD and Fotin-Mleczek M and Gnad-Vogt U	RNA-based adjuvant CV8102 enhances the immunogenicity of a licensed rabies vaccine in a first-in-human trial.

701720	Liu AY and Zhang J and Anderson PL and Wagner T and Pan Z and Peda M and Gomez K and Beamer M and Jacobson C and Strizki J and Dezzutti CS and Piper JM	Phase 1 Pharmacokinetic Trial of 2 Intravaginal Rings Containing Different Dose Strengths of Vicriviroc (MK-4176) and MK-2048.
701820	Launay O and Ndiaye AGW and Conti V and Loulergue P and ScirÃ© AS and Landre AM and Ferruzzi P and Nedjaai N and SchÃ¼tte LD and Auerbach J and Marchetti E and Saul A and Martin LB and Podda A	Booster Vaccination With GVGH Shigella sonnei 1790GAHB GMMA Vaccine Compared to Single Vaccination in Unvaccinated Healthy European Adults: Results From a Phase 1 Clinical Trial.
701830	Bachelez H and Choon SE and Marrakchi S and Burden AD and Tsai TF and Morita A and Turki H and Hall DB and Shear M and Baum P and Padula SJ and Thoma C	Inhibition of the Interleukin-36 Pathway for the Treatment of Generalized Pustular Psoriasis.
701870	Gaudinski MR and Coates EE and Novik L and Widge A and Houser KV and Burch E and Holman LA and Gordon IJ and Chen GL and Carter C and Nason M and Sitar S and Yamshchikov G and Berkowitz N and Andrews C and Vazquez S and Laurencot C and Misasi J and Arnold F and Carlton K and Lawlor H and Gall J and Bailer RT and McDermott A and Capparelli E and Koup RA and Mascola JR and Graham BS and Sullivan NJ and Ledgerwood JE	Safety, Tolerability, Pharmacokinetics, and Immunogenicity of mAb114: A Phase 1 Trial of a Therapeutic Monoclonal Antibody Targeting Ebola Virus Glycoprotein
701950	Pena LDM and Barohn RJ and Byrne BJ and Desnuelle C and Goker-Alpan O and Ladha S and LaforÃªt P and Mengel KE and Pestronk A and Pouget J and Schoser B and Straub V and Trivedi J and Van Damme P and Vissing J and Young P and Kacena K and Shafi R and Thurberg BL and Culm-Merdek K and van der Ploeg AT	Safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory efficacy of the novel enzyme replacement therapy avalglucosidase alfa (neoGAA) in treatment-naÃ¯ve and alglucosidase alfa-treated patients with late-onset Pompe disease: A phase 1, open-label, multicenter, multinational, ascending dose study.
701970	Weiser T and Weigmann H	Effect of Caffeine on the Bioavailability and Pharmacokinetics of an Acetylsalicylic Acid-Paracetamol Combination: Results of a Phase I Study.
702081	Furie R and Werth VP and Merola JF and Stevenson L and Reynolds TL and Naik H and Wang W and Christmann R and Gardet A and Pellerin A and Hamann S and Auluck P and Barbey C and Gulati P and Rabah D and Franchimont N	Monoclonal antibody targeting BDCA2 ameliorates skin lesions in systemic lupus erythematosus.
702082	Furie R and Werth VP and Merola JF and Stevenson L and Reynolds TL and Naik H and Wang W and Christmann R and Gardet A and Pellerin A and Hamann S and Auluck P and Barbey C and Gulati P and Rabah D and Franchimont N	Monoclonal antibody targeting BDCA2 ameliorates skin lesions in systemic lupus erythematosus.
702131	Zhao CY and Lv Y and Zhu Y and Wei MJ and Liu MY and Ji XW and Kang ZS and Xia YH and Tian JH and Ma Y and Liu Y	A First-in-Human Safety, Tolerability, and Pharmacokinetics Study of Benapenem in Healthy Chinese Volunteers.
702132	Zhao CY and Lv Y and Zhu Y and Wei MJ and Liu MY and Ji XW and Kang ZS and Xia YH and Tian JH and Ma Y and Liu Y	A First-in-Human Safety, Tolerability, and Pharmacokinetics Study of Benapenem in Healthy Chinese Volunteers.
702133	Zhao CY and Lv Y and Zhu Y and Wei MJ and Liu MY and Ji XW and Kang ZS and Xia YH and Tian JH and Ma Y and Liu Y	A First-in-Human Safety, Tolerability, and Pharmacokinetics Study of Benapenem in Healthy Chinese Volunteers.
702170	Noguchi LM and Hoesley C and Kelly C and Scheckter R and Bunge K and Nel A and Marzinke MA and Hendrix CW and Dezzutti	Pharmacokinetics of Dapivirine Transfer into Blood Plasma, Breast Milk, and Cervicovaginal Fluid of Lactating Women Using the Dapivirine Vaginal Ring.

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702190	Charnigo RJ and Beidler D and Rybin D and Pittman DD and Tan B and Howard J and Michelson AD and Frelinger AL , III and Clarke N	PF-04447943, a Phosphodiesterase 9A Inhibitor, in Stable Sickle Cell Disease Patients: A Phase Ib Randomized, Placebo-Controlled Study.
702300	Yuen F and Wu S and Thirumalai A and Swerdloff RS and Page ST and Liu PY and Dart C and Wu H and Blithe DL and Sitruk-Ware R and Long J and Bai F and Hull L and Bremner WJ and Anawalt BD and Wang C	Preventing secondary exposure to women from men applying a novel nestorone/testosterone contraceptive gel.
702330	Shaik N and Hee B and Wei H and LaBadie RR	Evaluation of the effects of formulation, food, or a proton-pump inhibitor on the pharmacokinetics of glasdegib (PF-04449913) in healthy volunteers: a randomized phase I study.
702380	Perry J and Trautman B and Takher-Smith J and Kramer S and Kane K and Silverman M and Tan L and Haughie S and Richter W and Kirkov V and Arsova S and Ward J and Hava DL	Particle size and gastrointestinal absorption influence tiotropium pharmacokinetics: a pilot bioequivalence study of PUR0200 and Spiriva HandiHaler.
702480	Gille A and Duffy D and Tortorici MA and Wright SD and Deckelbaum LI and D'Andrea DM	Moderate Renal Impairment Does Not Impact the Ability of CSL112 (Apolipoprotein A-I [Human]) to Enhance Cholesterol Efflux Capacity.
702510	Corrales O and HernÃ¡ndez L and Prada D and GÃ³mez J and Reyes Y and LÃ³pez AM and GonzÃ¡lez LJ and Del Carmen DomÃnguez Horta M	CIGB-814, an altered peptide ligand derived from human heat-shock protein 60, decreases anti-cyclic citrullinated peptides antibodies in patients with rheumatoid arthritis.
702540	de Boon WMI and van Esdonk MJ and Stuurman FE and Biermasz NR and Pons L and Paty I and Burggraaf J	A Novel Somatostatin-Dopamine Chimera (BIM23B065) Reduced GH Secretion in a First-in-Human Clinical Trial.
702570	Saiz-RodrÃguez M and Ochoa D and Herrador C and Belmonte C and RomÃ¡n M and Alday E and Koller D and Zubiaur P and MejÃa G and HernÃ¡ndez-MartÃnez M and Abad-Santos F	Polymorphisms associated with fentanyl pharmacokinetics, pharmacodynamics and adverse effects.
702580	Wu S and Yuen F and Swerdloff RS and Pak Y and Thirumalai A and Liu PY and Amory JK and Bai F and Hull L and Blithe DL and Anawalt BD and Parman T and Kim K and Lee MS and Bremner WJ and Page ST and Wang C	Safety and Pharmacokinetics of Single-Dose Novel Oral Androgen 11Î²-Methyl-19-Nortestosterone-17Î²-Dodecylcarbonate in Men.
702690	Jager U and D'Sa S and SchÃ¶rgenhofer C and Bartko J and Derhaschnig U and Sillaber C and Jilma-Stohlawetz P and Fillitz M and Schenk T and Patou G and Panicker S and Parry GC and Gilbert JC and Jilma B	Inhibition of complement C1s improves severe hemolytic anemia in cold agglutinin disease: a first-in-human trial.
702730	Walk J and de Bree LCJ and Graumans W and Stoter R and van Gemert GJ and van de Vegte-Bolmer M and Teelen K and Hermsen CC and Arts RJW and Behet MC and Keramati F and Moorlag SJCFM and Yang ASP and van Crevel R and Aaby P and de Mast Q and van der Ven AJAM and Stabell Benn C and Netea MG and Sauerwein RW	Outcomes of controlled human malaria infection after BCG vaccination.
702810	Medise BE and Soedjatmiko S and Rengganis I and Gunardi H and Sekartini R and Koesno S and Satari HI and Hadinegoro SR and Yang JS and Excler JL and Sahastrabuddhe S and Puspita M and Sari RM and Bachtiar NS	Six-month follow up of a randomized clinical trial-phase I study in Indonesian adults and children: Safety and immunogenicity of Salmonella typhi polysaccharide-diphtheria toxoid (Vi-DT) conjugate vaccine.

702860	Sardh E and Harper P and Balwani M and Stein P and Rees D and Bissell DM and Desnick R and Parker C and Phillips J and Bonkovsky HL and Vassiliou D and Penz C and Chan-Daniels A and He Q and Querbes W and Fitzgerald K and Kim JB and Garg P and Vaishnaw A and Simon AR and Anderson KE	Phase 1 Trial of an RNA Interference Therapy for Acute Intermittent Porphyria.
702870	Okuyama T and Eto Y and Sakai N and Minami K and Yamamoto T and Sonoda H and Yamaoka M and Tachibana K and Hirato T and Sato Y	Iduronate-2-Sulfatase with Anti-human Transferrin Receptor Antibody for Neuropathic Mucopolysaccharidosis II: A Phase 1/2 Trial.
702910	Aleo MD and Aubrecht J and D Bonin P and Burt DA and Colangelo J and Luo L and Schomaker S and Swiss R and Kirby S and C Rigdon G and Dua P	Phase I study of PFâ€ 04895162, a Kv7 channel opener, reveals unexpected hepatotoxicity in healthy subjects, but not rats or monkeys: clinical evidence of disrupted bile acid homeostasis.
703070	Whitley CB and Vijay S and Yao B and Pineda M and Parker GJM and Rojas-Caro S and Zhang X and Dai Y and Cinar A and Bubb G and Patki KC and Escolar ML	Final results of the phase 1/2, open-label clinical study of intravenous recombinant human N-acetyl-Î±-d-glucosaminidase (SBC-103) in children with mucopolysaccharidosis IIIB.
703080	Kong R and Laskin OL and Kaushik D and Jin F and Ma J and McIntosh J and Souza M and Almstead N	Ataluren Pharmacokinetics in Healthy Japanese and Caucasian Subjects.
703110	Zomorodi K and Kankam M and Lu Y	A Phase I, Randomized, Crossover, Open-label Study of the Pharmacokinetics of Solriamfetol (JZP-110) in Healthy Adult Subjects With and Without Food.
703120	Kurihara Y and Yamagami J and Funakoshi T and Ishii M and Miyamoto J and Fujio Y and Kakuta R and Tanikawa A and Aoyama Y and Iwatsuki K and Ishii N and Hashimoto T and Nishie W and Shimizu H and Kouyama K and Amagai M	Rituximab therapy for refractory autoimmune bullous diseases: A multicenter, open-label, single-arm, phase 1/2 study on 10 Japanese patients.
703270	Crooke ST and Baker BF and Xia S and Yu RZ and Viney NJ and Wang Y and Tsimikas S and Geary RS	Integrated Assessment of the Clinical Performance of GalNAc(3)-Conjugated 2'-O-Methoxyethyl Chimeric Antisense Oligonucleotides: I. Human Volunteer Experience.
703340	Zhang T and Chen G and Liu C and Zu L and Wang Q and Wang Y and Lv J and An Y and Dong L and Cheng H and Ren S and Wang Q and Zheng Q and Song H and Fang Y	A Phase I Study Comparing the Pharmacokinetics, Safety, and Immunogenicity of Proposed Biosimilar GB242 and Reference Infliximab in Healthy Subjects.
703360	Rosenzwajg M and Lorenzon R and Cacoub P and Pham HP and Pitoiset F and El Soufi K and RIbet C and Bernard C and Aractingi S and Banneville B and Beaugerie L and Berenbaum F and Champey J and Chazouilleres O and Corpechot C and Fautrel B and Mekinian A and Regnier E and Saadoun D and Salem JE and Sellam J and Seksik P and Daguenel-Nguyen A and Doppler V and Mariau J and Vicaut E and Klatzmann D	Immunological and clinical effects of low-dose interleukin-2 across 11 autoimmune diseases in a single, open clinical trial.
703560	Thirumalai A and Ceponis J and Amory JK and Swerdloff R and Surampudi V and Liu PY and Bremner WJ and Harvey E and Blithe DL and Lee MS and Hull L and Wang C and Page ST	Effects of 28 Days of Oral Dimethandrolone Undecanoate in Healthy Men: A Prototype Male Pill.
703580	Kobayashi K and Suzuki Y and Watanabe K and Oda K and Mukae M and Yamada A and Yamagami H and Nishimura A and Okamoto H	A Phase 1, Multiple-Dose Study of Vedolizumab in Japanese Patients With Ulcerative Colitis.

703600	Ellis J and van Maurik A and Fortunato L and Gisbert S and Chen K and Schwartz A and McHugh S and Want A and Santos Franco S and Oliveira JJ and Price J and Coles A and Brown K and Su D and Craigen JL and Yang J and Brett S and Davis B and Cheriyan J and Kousin-Ezewu O and Gray F and Thompson PW and Fernando D	Anti-IL-7 receptor Î± monoclonal antibody (GSK2618960) in healthy subjects - a randomized, double-blind, placebo-controlled study.
703630	Pathak S and Vince B and Kelsh D and Shram MJ and Setnik B and Lu H and Nangia N and Stanford AD and Ehrich E	Abuse Potential of Buprenorphine/Samidorphan Combination Compared to Buprenorphine and Placebo: A Phase 1 Randomized Controlled Trial.
703641	Yang H and Merica E and Chen Y and Cohen M and Goldwater R and Kosinski PA and Kung C and Yuan ZJ and Silverman L and Goldwasser M and Silver BA and Agresta S and Barbier AJ	Phase 1 Single- and Multiple-Ascending-Dose Randomized Studies of the Safety, Pharmacokinetics, and Pharmacodynamics of AG-348, a First-in-Class Allosteric Activator of Pyruvate Kinase R, in Healthy Volunteers.
703642	Yang H and Merica E and Chen Y and Cohen M and Goldwater R and Kosinski PA and Kung C and Yuan ZJ and Silverman L and Goldwasser M and Silver BA and Agresta S and Barbier AJ	Phase 1 Single- and Multiple-Ascending-Dose Randomized Studies of the Safety, Pharmacokinetics, and Pharmacodynamics of AG-348, a First-in-Class Allosteric Activator of Pyruvate Kinase R, in Healthy Volunteers.
703720	Dooner H and Mundin G and Mersmann S and Bennett C and Lorch U and Encabo M and Escriche M and Encina G and Smith K	Pharmacokinetics of Tramadol and Celecoxib in Japanese and Caucasian Subjects Following Administration of Co-Crystal of Tramadol-Celecoxib (CTC): A Randomised, Open-Label Study.
703740	Dhaliwal S and Rybak I and Ellis SR and Notay M and Trivedi M and Burney W and Vaughn AR and Nguyen M and Reiter P and Bosanac S and Yan H and Foolad N and Sivamani RK	Prospective, randomized, double-blind assessment of topical bakuchiol and retinol for facial photoageing.
703751	Zha J and Ding B and Wang H and Zhao W and Yu C and Alves K and Mobashery N and Luo Y and Menon RM	Pharmacokinetics of Ombitasvir, Paritaprevir, Ritonavir, and Dasabuvir in Healthy Chinese Subjects and HCV GT1b-Infected Chinese, South Korean and Taiwanese Patients.
703752	Zha J and Ding B and Wang H and Zhao W and Yu C and Alves K and Mobashery N and Luo Y and Menon RM	Pharmacokinetics of Ombitasvir, Paritaprevir, Ritonavir, and Dasabuvir in Healthy Chinese Subjects and HCV GT1b-Infected Chinese, South Korean and Taiwanese Patients.
703770	Maes A and DePetrillo P and Siddiqui S and Reisner C and Dorinsky P	Pharmacokinetics of Co-Suspension Delivery Technology Budesonide/Glycopyrronium/Formoterol Fumarate Dihydrate (BGF MDI) and Budesonide/Formoterol Fumarate Dihydrate (BFF MDI) Fixed-Dose Combinations Compared With an Active Control: A Phase 1, Randomized, Single-Dose, Crossover Study in Healthy Adults.
703800	Hall J and Gillen M and Yang X and Shen Z	Pharmacokinetics, Pharmacodynamics, and Tolerability of Concomitant Administration of Verinurad and Febuxostat in Healthy Male Volunteers.
703840	Agius MA and Klodowska-Duda G and Maciejowski M and Potemkowski A and Li J and Patra K and Wesley J and Madani S and Barron G and Katz E and Flor A	Safety and tolerability of inebilizumab (MEDI-551), an anti-CD19 monoclonal antibody, in patients with relapsing forms of multiple sclerosis: Results from a phase 1 randomised, placebo-controlled, escalating intravenous and subcutaneous dose study.
703920	Bernstein DI and Pasetti MF and Brady R and Buskirk AD and Wahid R and Dickey M and Cohen M and Baughman H and El-Khorazaty J and Maier N and Sztein MB and Baqar S and Bourgeois AL	A Phase 1 dose escalating study of double mutant heat-labile toxin LTR192G/L211A (dmLT) from Enterotoxigenic Escherichia coli (ETEC) by sublingual or oral immunization.
703950	Maurizi A and De Luca F and Zanghi A and Manzi E and Leonardo C and Guidotti M and Antonaccio FP and Olivieri V and De Dominicis C	The role of nutraceutical medications in men with non bacterial chronic prostatitis and chronic pelvic pain syndrome: A prospective non blinded study utilizing flower pollen extracts versus bioflavonoids.

703961	Steiner-Monard V and Kamaka K and Karoui O and Roethlisberger S and Audran R and Daubenberger C and Fayet-Mello A and Erdmann-Voisin A and Felger I and Geiger K and Govender L and Houard S and Huber E and Mayor C and Mkindi C and Portevin D and Rusch S and Schmidlin S and Tiendrebeogo RW and Theisen M and Thierry AC and Vallotton L and Corradin G and Leroy O and Abdulla S and Shekalaghe S and Genton B and Spertini F and Jongo SA	The Candidate Blood-stage Malaria Vaccine P27A Induces a Robust Humoral Response in a Fast Track to the Field Phase 1 Trial in Exposed and Nonexposed Volunteers.
703962	Steiner-Monard V and Kamaka K and Karoui O and Roethlisberger S and Audran R and Daubenberger C and Fayet-Mello A and Erdmann-Voisin A and Felger I and Geiger K and Govender L and Houard S and Huber E and Mayor C and Mkindi C and Portevin D and Rusch S and Schmidlin S and Tiendrebeogo RW and Theisen M and Thierry AC and Vallotton L and Corradin G and Leroy O and Abdulla S and Shekalaghe S and Genton B and Spertini F and Jongo SA	The Candidate Blood-stage Malaria Vaccine P27A Induces a Robust Humoral Response in a Fast Track to the Field Phase 1 Trial in Exposed and Nonexposed Volunteers.
704080	Tshilolo L and Tomlinson G and Williams TN and Santos B and Olupot-Olupot P and Lane A and Aygun B and Stuber SE and Latham TS and McGann PT and Ware RE	Hydroxyurea for Children with Sickle Cell Anemia in Sub-Saharan Africa.
704161	Qiu R and Ahn JE and Alexander R and Brodney MA and He P and Leurent C and Mancuso J and Margolin RA and Tankisheva E and Chen D	Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Effects of PF-06751979, a Potent and Selective Oral BACE1 Inhibitor: Results from Phase I Studies in Healthy Adults and Healthy Older Subjects.
704162	Qiu R and Ahn JE and Alexander R and Brodney MA and He P and Leurent C and Mancuso J and Margolin RA and Tankisheva E and Chen D	Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Effects of PF-06751979, a Potent and Selective Oral BACE1 Inhibitor: Results from Phase I Studies in Healthy Adults and Healthy Older Subjects.
704163	Qiu R and Ahn JE and Alexander R and Brodney MA and He P and Leurent C and Mancuso J and Margolin RA and Tankisheva E and Chen D	Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Effects of PF-06751979, a Potent and Selective Oral BACE1 Inhibitor: Results from Phase I Studies in Healthy Adults and Healthy Older Subjects.
704171	Edwards CV and Bhutani D and Mapara M and Radhakrishnan J and Shames S and Maurer MS and Leng S and Wall JS and Solomon A and Eisenberger A and Lentzsch S	One year follow up analysis of the phase 1a/b study of chimeric fibril-reactive monoclonal antibody 11-1F4 in patients with AL amyloidosis.
704172	Edwards CV and Bhutani D and Mapara M and Radhakrishnan J and Shames S and Maurer MS and Leng S and Wall JS and Solomon A and Eisenberger A and Lentzsch S	One year follow up analysis of the phase 1a/b study of chimeric fibril-reactive monoclonal antibody 11-1F4 in patients with AL amyloidosis.
704270	Raqib R and Sarker P and Zaman K and Alam NH and Wierzba TF and Maier N and Talukder K and Baqui AH and Suvarnapunya AE and Qadri F and Walker RI and Fix A and Venkatesan MM	A phase I trial of WRSS1, a Shigella sonnei live oral vaccine in Bangladeshi adults and children.
704281	Li L and Zhen EY and Decker RL and Willis BA and Waters D and Liu P and Hake AM and Demattos RB and Ayan-Oshodi M	Pharmacokinetics and Pharmacodynamics of LY2599666, a PEG-Linked Antigen Binding Fragment that Targets Soluble Monomer Amyloid-Î².
704282	Li L and Zhen EY and Decker RL and Willis BA and Waters D and Liu P and Hake AM and Demattos RB and Ayan-Oshodi M	Pharmacokinetics and Pharmacodynamics of LY2599666, a PEG-Linked Antigen Binding Fragment that Targets Soluble Monomer Amyloid-Î².

704300	Nakayama T and Eda M and Hirano M and Goto W	Immunogenicity and safety of the new MMR vaccine containing measles AIK-C, rubella Takahashi, and mumps RIT4385 strains in Japanese children: a randomized phase I/II clinical trial.
704381	Kletzl H and Marquet A and GÃ¼nther A and Tang W and Heuberger J and Groeneveld GJ and Birkhoff W and Mercuri E and LochmÃ¼ller H and Wood C and Fischer D and Gerlach I and Heinig K and Bugawan T and Dziadek S and Kinch R and Czech C and Khwaja O	The oral splicing modifier RG7800 increases full length survival of motor neuron 2 mRNA and survival of motor neuron protein: Results from trials in healthy adults and patients with spinal muscular atrophy.
704382	Kletzl H and Marquet A and GÃ¼nther A and Tang W and Heuberger J and Groeneveld GJ and Birkhoff W and Mercuri E and LochmÃ¼ller H and Wood C and Fischer D and Gerlach I and Heinig K and Bugawan T and Dziadek S and Kinch R and Czech C and Khwaja O	The oral splicing modifier RG7800 increases full length survival of motor neuron 2 mRNA and survival of motor neuron protein: Results from trials in healthy adults and patients with spinal muscular atrophy.
704400	Gohler K and Sokolowska M and Schoedel KA and Nemeth R and Kleideiter E and Szeto I and Eerdekens MH	Assessment of the Abuse Potential of Cebranopadol in Nondependent Recreational Opioid Users: A Phase 1 Randomized Controlled Study.
704420	Yam JC and Jiang Y and Tang SM and Law AKP and Chan JJ and Wong E and Ko ST and Young AL and Tham CC and Chen LJ and Pang CP	Low-Concentration Atropine for Myopia Progression (LAMP) Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of 0.05%, 0.025%, and 0.01% Atropine Eye Drops in Myopia Control.
704430	Finanger E and Vandenborne K and Finkel RS and Lee Sweeney H and Tennekoon G and Yum S and Mancini M and Bista P and Nichols A and Liu H and Fretzen A and Donovan JM	Phase 1 Study of Edasalonexent (CAT-1004), an Oral NF-Î°B Inhibitor, in Pediatric Patients with Duchenne Muscular Dystrophy.
704450	Manoff SB and Sausser M and Falk Russell A and Martin J and Radley D and Hyatt D and Roberts CC and Lickliter J and Krishnarajah J and Bett A and Dubey S and Finn T and Coller BA	Immunogenicity and safety of an investigational tetravalent recombinant subunit vaccine for dengue: results of a Phase I randomized clinical trial in flavivirus-naÃ¯ve adults.
704480	Shimizu T and Nakayama Y and Ishii E and Ida S and Satou T and Tokuhara D and Arai K and Nii M and Rydholm H and Yajima T	Oral esomeprazole in Japanese pediatric patients with gastric acid-related disease: Safety, efficacy, and pharmacokinetics.
704530	Preston RA and Mamikonyan G and DeGraff S and Chiou J and Kemper CJ and Xu A and Mastim M and Yeole R and Chavan R and Patel A and Friedland HD and Bhatia A	Single-Center Evaluation of the Pharmacokinetics of WCK 5222 (Cefepime-Zidebactam Combination) in Subjects with Renal Impairment.
704560	Mason JW and Chugh R and Patel A and Gutte R and Bhatia A	Electrocardiographic Effects of a Supratherapeutic Dose of WCK 2349, a Benzoquinolizine Fluoroquinolone.
704610	Boyd B and Smith S and Gammaitoni A and Galer BS and Farfel GM	A phase I, randomized, open-label, single-dose, 3-period crossover study to evaluate theÂ drug-drug interaction between ZX008 (fenfluramine HCl oral solution) and a regimen of stiripentol, clobazam, and valproate in healthy subjectsâ€©.
704651	Sturm S and GÃ¼nther A and Jaber B and Jordan P and Al Kotbi N and Parkar N and Cleary Y and Frances N and Bergauer T and Heinig K and Kletzl H and Marquet A and Ratni H and Poirier A and MÃ¼ller L and Czech C and Khwaja O	A phase 1 healthy male volunteer single escalating dose study of the pharmacokinetics and pharmacodynamics of risdiplam (RG7916, RO7034067), a SMN2 splicing modifier.
704652	Sturm S and GÃ¼nther A and Jaber B and Jordan P and Al Kotbi N and Parkar N and Cleary Y and Frances N and Bergauer T and Heinig K and Kletzl H and Marquet A and Ratni H and Poirier A and MÃ¼ller L and Czech C and Khwaja O	A phase 1 healthy male volunteer single escalating dose study of the pharmacokinetics and pharmacodynamics of risdiplam (RG7916, RO7034067), a SMN2 splicing modifier.

704670	Jault P and Leclerc T and Jennes S and Pirnay JP and Que YA and Resch G and Rousseau AF and Ravat F and Carsin H and Le Floch R and Schaal JV and Soler C and Fevre C and Arnaud I and Bretaudeau L and Gabard J	Efficacy and tolerability of a cocktail of bacteriophages to treat burn wounds infected by Pseudomonas aeruginosa (PhagoBurn): a randomised, controlled, double-blind phase 1/2 trial.
704680	Sumi E and Nomura T and Asada R and Uozumi R and Tada H and Amino Y and Sawada T and Yonezawa A and Hagiwara M and Kabashima K	Safety and Plasma Concentrations of a Cyclin-dependent Kinase 9 (CDK9) Inhibitor, FIT039, Administered by a Single Adhesive Skin Patch Applied on Normal Skin and Cutaneous Warts.
704700	Elliot ER and Cerrone M and Challenger E and Else L and Amara A and Bisdomini E and Khoo S and Owen A and Boffito M	Pharmacokinetics of dolutegravir with and without darunavir/cobicistat in healthy volunteers.
704740	Narushima K and Maeda H and Shiramoto M and Endo Y and Ohtsuka S and Nakamura H and Nagata Y and Uchimura T and Kannami A and Shimazaki R and Fukagawa M and Akizawa T	Assessment of CYP-Mediated Drug Interactions for Evocalcet, a New Calcimimetic Agent, Based on In Vitro Investigations and a Cocktail Study in Humans.
704780	Vourvahis M and McFadyen L and Nepal S and Valluri SR and Fang A and Fate GD and Wood LS and Marshall JC and Chan PLS and Nedderman A and Haynes J and Savage ME and Clark A and Smith KY and Heera J	No Clinical Impact of CYP3A5 Gene Polymorphisms on the Pharmacokinetics and/or Efficacy of Maraviroc in Healthy Volunteers and HIV-1-Infected Subjects.
704790	Elgart A and Zur AA and Mimrod D and Dror V and Bar-Ilan O and Korver T and Spiegelstein O	The effect of laquinimod, a novel immuno-modulator in development to treat Huntington disease, on the pharmacokinetics of ethinylestradiol and levonorgestrel in healthy young women.
704800	Sohn WY and Portale AA and Salusky IB and Zhang H and Yan LL and Ertik B and Shahinfar S and Lee E and Dehmel B and Warady BA	An open-label, single-dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of cinacalcet in pediatric subjects aged 28Â days to <â€‰6Â years with chronic kidney disease receiving dialysis.
704880	Rothenberg ME and Wang Y and Lekkerkerker A and Danilenko DM and Maciuca R and Erickson R and Herman A and Stefanich E and Lu TT	Randomized Phase I Healthy Volunteer Study of UTTR1147A (IL-22Fc): A Potential Therapy for Epithelial Injury.
704890	Wring S and Murphy G and Atiee G and Corr C and Hyman M and Willett M and Angulo D	Clinical Pharmacokinetics and Drug-Drug Interaction Potential for Coadministered SCY-078, an Oral Fungicidal Glucan Synthase Inhibitor, and Tacrolimus.
704910	Elkashef A and BraÅ¡iÄ‡ JR and Cantelina LR Jr and Kahn R and Chiang N and Ye W and Zhou Y and Mojsiak J and Warren KR and Crabb A and Hilton J and Wong DF and Vocci F	A cholecystokinin B receptor antagonist and cocaine interaction, phase I study.
704930	Ino H and Endo A and Wakamatsu A and Ogura H and Numachi Y and Kendrick S	Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Evaluations Following Single Oral Doses of GSK2330672 in Healthy Japanese Volunteers.
704950	de Hoon J and Van Hecken A and Vandermeulen C and Herbots M and Kubo Y and Lee E and Eisele O and Vargas G and Gabriel K	Phase 1, randomized, parallel-group, double-blind, placebo-controlled trial to evaluate the effects of erenumab (AMG 334) and concomitant sumatriptan on blood pressure in healthy volunteers.
704961	Hauser RA and Pahwa R and Wargin WA and Souza-Prien CJ and McClure N and Johnson R and Nguyen JT and Patni R and Went GT	Pharmacokinetics of ADS-5102 (Amantadine) ExtendedÂ Release Capsules Administered Once Daily at Bedtime for the Treatment of Dyskinesia.
704962	Hauser RA and Pahwa R and Wargin WA and Souza-Prien CJ and McClure N and Johnson R and Nguyen JT and Patni R and Went GT	Pharmacokinetics of ADS-5102 (Amantadine) ExtendedÂ Release Capsules Administered Once Daily at Bedtime for the Treatment of Dyskinesia.
704980	Massarella J and Ariyawansa J and Natarajan J and Francke S and Murtaugh T and DeLemos B and Vaughan S and Fonseca S	Tramadol Hydrochloride at Steady State Lacks Clinically Relevant QTc Interval Increases in Healthy Adults.

704990	Cohen F	Open-Label, Dose-Escalation, Phase 1 Study of Safety and Single and Multiple-Dose Pharmacokinetics of Dichlorphenamide in Healthy Volunteers.
705020	Wang EQ and Plotka A and Salageanu J and Baltrukonis D and Mridha K and Frederich R and Sullivan BE	Comparative Pharmacokinetics and Pharmacodynamics of Bococizumab Following a Single Subcutaneous Injection Using Drug Substance Manufactured at Two Sites or Administration via Two Different Devices.
705050	Fleming J and Hernandez G and Hartman L and Maksimovic J and Nace S and Lawler B and Risa T and Cook T and Agni R and Reichelderfer M and Luzzio C and Rolak L and Field A and Fabry Z	Safety and efficacy of helminth treatment in relapsing-remitting multiple sclerosis: Results of the HINT 2 clinical trial.

Appendix D. Data Spreadsheet

Starts on the following page.