Research Data Request: Placebo Rates in Inflammatory Bowel Disease: An Individual Patient Data Meta-analysis of Randomized Controlled Trials

Vivli ID: 00007288

Comments from the Vivli Team

In the last round of review, Wellcome Trust IRP requested revisions. As a result, PI updated the Narrative Summary and the Publication and Dissemination Plan. For detailed information on the changes made, please see attachment ‘2021_11_29 Vivli ID 00007288_form check comparison report’ in chat. Data contributors are provided with the opportunity to review the proposal with these revisions.

Research Team

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Education or Qualifications
Chief Medical Officer at Alimentiv and a Clinician Scientist and holds dual appointments as Professor in the Departments of Medicine (Division of Gastroenterology) and cross-appointment to Epidemiology and Biostatistics at The University of Western Ontario.
2014 - Post Graduate Diploma, London School of Hygiene and Tropical Medicine, Clinical Trials
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Conflicts of Interest and Plan for Management
Received consulting fees from AbbVie, Alimentiv Inc (formerly Robarts Clinical Trials), Arena pharmaceuticals, Bristol Myers Squibb, Celtrion, Eli Lilly, Ferring, Fresenius Kabi, GlaxoSmithKline, Genentech, Gilead, Janssen, Merck, Mylan, Pendopharm, Pfizer, Roche, Sandoz, Takeda, Topivert; speaker’s fees from, Abbvie, Ferring, Janssen Pfizer Shire, Takeda. The research outlined in this study is not receiving funding from any of the outlined companies with the exception of Alimentiv Inc which is the sponsor and funder of this study.

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Conflicts of Interest and Plan for Management
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Conflicts of Interest and Plan for Management
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**Conflicts of Interest and Plan for Management**
None

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**Conflicts of Interest and Plan for Management**
Received consulting fees from AbbVie, Alimentiv Inc. (formerly Robarts Clinical Trials Inc.), Amgen, AVIR Pharma Inc, Ferring, Fresenius Kabi, Janssen, Mylan, Takeda, Pfizer, Roche; speaker’s fees from AbbVie, AVIR Pharma Inc, Janssen, Takeda, and Pfizer; research support from Pfizer. The research outlined in this study is not receiving funding from any of the outlined companies with the exception of Alimentiv Inc which is the sponsor and funder of this study.

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**Education or Qualifications**
N/A

**Conflicts of Interest and Plan for Management**
N/A

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**Conflicts of Interest and Plan for Management**
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Research Proposal

General

Title of Proposed Research
Placebo Rates in Inflammatory Bowel Disease: An Individual Patient Data Meta-analysis of Randomized Controlled Trials

Narrative summary explaining the relevance of the project to science and public health

Inflammatory bowel disease (IBD) is a condition that causes swelling and pain in the digestive tract, which is the tube that carries food from the mouth to the stomach and subsequently to the anus. IBD is a common disease and 6.8 million people around the world suffer from it – and that number is growing (Global Burden of Disease Inflammatory Bowel Disease Collaborators, 2020). While there is no cure for IBD, there are several therapies available to treat the disease and more that are in development.

To learn whether a new therapy works to treat IBD, it must be tested in research studies. One way to do this is to compare the therapy to a placebo, which is a “fake” copy of the real therapy. The placebo looks like the real therapy, but it contains none of the medicine. In such a study, some IBD patients will be given therapy while others will be given placebo. Usually this is decided randomly (like the flip of a coin) and neither the patients nor their doctors know what they are taking until the study is over. If the therapy works, the group treated with the real therapy should do better than the group that received the placebo. Sometimes a therapy works very well and there is a big difference between the groups; other times the therapy has a small effect, or none at all, and the difference between the groups is lessened or disappears. But seeing the real benefit of a new therapy is made harder by something called the “placebo effect.” The placebo effect is a benefit that a person feels because of their belief in a therapy even though the improvement is not due to the therapy itself. For example, in a study where participants do not know if they are receiving therapy or placebo, it is common for those in the placebo group to still report some improvement in symptoms despite not receiving any medicine (Elsenbruch et al., 2015). There are many possible reasons for the placebo effect and previous research has identified several study-specific factors that contribute (Jairath et al., 2017; Jairath et al., 2020; Duijvestein et al., 2020). However, more research is needed.

In this study, we want to take a close look at both study factors and independent study participant characteristics that are linked to the placebo effect. By identifying these factors, this study aims to estimate placebo response in IBD studies and improve the design of future studies in IBD by reducing the impact of the placebo effect and making it easier to estimate the real benefit of any new therapies.

Aims/Objectives and Hypotheses

The primary objective of this study is to estimate the placebo clinical response and remission rates in induction and maintenance periods of CD and UC trials and identify factors influencing these rates.

The secondary objectives of this study are to:
1. Estimate the response and remission rates (including endoscopic, histologic, and clinical based definitions) in induction and maintenance periods of CD and UC trials and identify factors influencing these rates.
2. Assess the primary objective and secondary objective 1 in Tumor Necrosis Factor (TNF) antagonist-naive and TNF antagonist-exposed subjects.
3. Assess the primary objective and secondary objective 1 according to the number of biologics previously exposed to, and class of biologic.
4. Determine factors associated with placebo hyper-response in induction and maintenance periods of CD and UC trials.
5. Estimate the adverse event (AE) and serious adverse event (SAE) rates in induction and maintenance periods of CD and UC trials and identify factors influencing the rates and severity.

Exploratory objectives of this study are to determine:
1. The molecular profile (protein and/or ribonucleic acid (RNA) levels) predicting placebo response in subjects with available molecular data.
2. The impact of central reading and adjudication models on placebo rates, if these data are available.

Since meta-analyses are not hypothesis-testing activities, there is no specific hypothesis. We hope to increase the precision of the estimates for the placebo rates.

Purpose of Analysis

Participant-level data meta-analysis

Support clinical trial design

Study Design

Brief Description

This study is an individual participant data (IPD) meta-analysis to investigate factors affecting placebo rates in IBD RCTs while minimizing bias arising from the heterogeneity of analyzing protocols between trials. IPD will be obtained for subjects randomized to the placebo group in published phase 2 and 3 induction and maintenance RCTs evaluating the safety and efficacy of biologics and small molecule drugs in moderately to severely active CD and UC. Studies were identified by systematic review of all phase 2 and phase 3 trials from the last 10 years (2010-2021). IPD (e.g., baseline demographic, disease, and clinical characteristics, concomitant medications, previous exposure to biologics, molecular profile) will be obtained and subject, disease, clinical, and trial characteristics that may be associated with a placebo response in clinical and endoscopic disease activity will be identified for induction and maintenance trials.

A search of MEDLINE (1948-January 2020), EMBASE (1947-January 2020), the Cochrane Central Register of Controlled Trials (2020), and the Cochrane IBD/Functional Bowel Disorders review group specialized trials register was performed without language restriction from inception to January 2020 for all published induction and maintenance RCTs in CD and UC. Published trials were reviewed to identify all RCTs published since 2010, evaluating the safety and efficacy of biologics or small molecule drugs for moderately to severely active CD and UC.

Both two-stage and one-stage meta-analyses will be conducted for outcome data. In the two-stage analysis, proportions from all studies will be pooled using conventional
meta-analysis methods. This data will also be used to investigate how characteristics of studies may affect study-aggregate proportions using metaregression and/or study-subgroup analyses (i.e., based on previous TNF experience and number and class of biologics). For metaregression analyses, continuous factors will be centered and unadjusted estimates (95% 2-sided confidence intervals (CIs)) for outcome proportions obtained, as well as, estimates adjusted by important factors.

Statistical analyses will be performed on the data received, using a complete-case analysis basis. Depending on the severity of missing data, we will attempt to use multiple imputation as a sensitivity analysis.

The requested data will enable us to answer our “hypothesis” by allowing us to compute the pooled proportions at both the study-level (two-stage analysis) and the individual patient-level (one-stage analysis).

Outcome Elements Categorization/Definitions

DISEASE ACTIVITY MEASURES

The following will be reported for the baseline (Week 0) and primary endpoint assessment visits for both induction and maintenance periods:

UC Trials:
1. Mayo Clinic Score (MCS) (median, interquartile range (IQR))
2. Each subcomponent of the MCS (median, IQR)
3. Change in the total MCS score and change in each subcomponent of the MCS
4. Geboes Score (median, IQR)
5. Change in Geboes Score
6. Robarts Histopathology Index (RHI) score (calculated from Geboes subscores, if available) (median, IQR) Change in RHI score

CD TRIALS
1. Crohn’s Disease Activity Index (CDAI) (mean, standard deviation (SD), median, IQR)
2. Each subcomponent of the CDAI, if available
3. Change in the total CDAI from baseline and change in each component of the CDAI
4. 2-item patient-reported outcome (PRO2), if stool frequency (SF) and abdominal pain (AP) subscores of the CDAI are available (median, IQR) Change in PRO2 scores
5. Simple Endoscopic Score for Crohn’s Disease (SES-CD)/Crohn’s Disease Endoscopic Index of Severity (CDEIS) (median, IQR)
6. Each subcomponent of the SES-CD/CDEIS, per segment
7. Change in total SES-CD/CDEIS score and change in each component of the SES-CD/CDEIS, per segment
8. Total, colonic, and ileal Global Histologic Disease Activity Score (GHAS) (median, IQR), if available
9. Change in total, colonic, and ileal GHAS, if available

Both Trials
1. Albumin levels (median, IQR)
2. Change in albumin levels
3. C-reactive protein (CRP) levels (median, IQR)
4. Change in CRP levels
5. Fecal calprotectin (FCP) levels (median, IQR)
6. Change in FCP levels
7. Fecal lactoferrin levels (median, IQR)
8. Change in fecal lactoferrin levels
9. Health-related quality of life (HRQOL) index score (median, IQR)
10. Change in HRQOL index score

IMPROVEMENT IN DISEASE ACTIVITY INDICES:

UC Trials
Clinical Response: Clinical response (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

As different definitions for clinical response have been used in UC trials, we will also assess the placebo response rates based on these definitions of clinical response:
- Decrease in the MCS of ≥3 points and ≥30% reduction from baseline AND a ≥1-point decrease in rectal bleeding (RB) or an absolute RB subscore ≤1
- Decrease in the Adapted MCS (MCS with physician global assessment excluded) of ≥2 points and a ≥35% reduction from baseline to achieve a SF ≤1, and RB = 0

Clinical Remission: Clinical remission at the primary endpoint visit (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

As different definitions for clinical remission have been used in UC trials, we will also assess the placebo remission rates based on these definitions of clinical remission:
1. MCS ≤2 with no subscore > 1
2. Mayo Endoscopic Subscore (MES) ≤1, a ≥1-point decrease in SF from baseline to achieve a SF ≤1, and RB = 0

Sustained Clinical Remission: Sustained clinical remission, will be defined as, clinical remission based upon the above definitions at both the end of induction and maintenance periods.

Corticosteroid-free Clinical Remission: Corticosteroid-free clinical remission at the primary endpoint visit (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

As different definitions for clinical remission have been used in UC trials, we will also assess the placebo remission rates based on these definitions of corticosteroid-free clinical remission:
1. MCS ≤2 with no subscore > 1 and not receiving oral corticosteroids
2. MES ≤1, SF ≤1, and RB = 0 and not receiving oral corticosteroids

Sustained Corticosteroid-free Clinical Remission: Sustained clinical remission, will be defined as a subject who is in clinical remission based upon the above definitions at the end of both induction and maintenance periods.
Endoscopic Response: An endoscopic response (defined as a MES ≤ 1) at the primary endpoint visit of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

Endoscopic Remission: Endoscopic remission (defined as a MES = 0) at the primary endpoint visit of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

Histologic Response: Histologic response at the primary endpoint visit (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

Where possible, we will also assess the placebo response rates based on these definitions of histologic response for trials with histologic data:
1. Geboes Score < 3.1
2. A 7-point decrease from baseline in the RHI score

Histologic Remission: Histologic remission at the primary endpoint visit (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

Where possible, we will also assess the placebo remission rates based on these definitions of histologic remission for trials with histologic data:
- Geboes Score < 2.0
- Geboes subscores of 0 for neutrophils in lamina propria, neutrophils in epithelium, and erosions or ulcerations
- RHI ≤ 3 with subscores of 0 for lamina propria neutrophils and neutrophils in epithelium

CD trials:

Clinical Response: Clinical response (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no). As different definitions for clinical response have been used in CD trials, we will also assess the placebo response rates based upon these definitions of clinical response if data is available:
1. A 50% decrease in the total GHAS from baseline to the primary endpoint visit of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).
2. A 50% reduction from baseline in the SES-CD/CDEIS ≥ 1.0, with neither worse than baseline score at both the end of induction and maintenance periods.
3. A 25% reduction from baseline in the SES-CD/CDEIS ≥ 2.0
4. A decrease from baseline in the PRO2 of 8 points

Clinical Remission: Clinical remission at the primary endpoint visit (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

We will also assess the placebo remission rates based on other common definitions of clinical remission, if data is available:
1. CDAI < 150 points
2. PRO2 ≤ 8 points
3. SF ≤ 1.5 and AP ≤ 1.0, with neither worse than baseline score

Sustained Clinical Remission: Sustained clinical remission, will be defined as a subject who is in clinical remission based upon the above definitions (i.e., as defined in the trial, CDAI < 150 points, PRO2 ≤ 2 points, SF≤1.5, and AP≤1.0, with neither worse than baseline score) at both the end of induction and maintenance periods.

Corticosteroid-free Clinical Remission: Corticosteroid-free clinical remission at the primary endpoint visit (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

We will also assess the placebo remission rates based on other common definitions of corticosteroid-free clinical remission, if data is available:
1. CDAI < 150 points and not receiving oral corticosteroids
2. PRO2 ≤ 8 points and not receiving oral corticosteroids
3. SF ≤ 1.5 and AP ≤ 1.0, with neither being worse than baseline score and not receiving oral corticosteroids

Sustained Corticosteroid-free Clinical Remission: Sustained corticosteroid-free clinical remission, will be defined as a subject who is in clinical remission based upon the above definitions (i.e., as defined in the trial, CDAI < 150 points, PRO2 ≤ 2 points, SF≤1.5, and AP≤1.0, with neither worse than baseline score) at both the end of induction and maintenance periods.

Endoscopic Response: Endoscopic response (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

We will also assess the placebo response rates based on other common definitions of endoscopic response.
1. A ≥25% reduction from baseline in the SES-CD/CDEIS
2. A ≥50% reduction from baseline in the SES-CD/CDEIS

Endoscopic Remission: Endoscopic remission at the primary endpoint visit (as defined in the trial) of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

We will also assess the placebo remission rates based on other common definitions of endoscopic remission:
1. SES-CD/CDEIS ≤ 4, or ≤2 for isolated ileitis
2. SES-CD/CDEIS ≤ 2

Histologic Response: 250% decrease in the total GHAS from baseline to the primary endpoint visit of the induction period and the maintenance period (if applicable) will be dichotomized into a binary response (yes/no).

Main Predictor / Independent Variable

The following outcomes will be collected for both UC and CD trials. Their definitions will be taken directly from their respective trial.

Remission
1) Clinical Remission
2) Endoscopic Remission
3) Histologic Remission
4) Sustained Clinical Remission
5) Corticosteroid-free Clinical Remission
6) Sustained Corticosteroid-free Clinical Remission
Bayesian information criterion. Adjusted proportions will be obtained from the final model with independent variables centered. Measures) associated with the placebo response/remission rates using the various definitions and study-subgroups. The final model for each outcome will be based on Baseline/demographic characteristics and disease activity measures will be analyzed using the combined data, separately, for induction, maintenance phases and study-subgroup analyses (i.e., based on previous tumor necrosis factor (TNF) experience and number and class of biologics) of placebo group in published phase 2 and 3 induction and maintenance RCTs evaluating the safety and efficacy of biologics and small molecule drugs in moderately to severely active CD and UC. Studies were identified by systematic review of all phase 2 and phase 3 trials from the last 10 years (2010-present). List of variables are attached for the data extraction. IPD (e.g., baseline demographic, disease, and clinical characteristics, concomitant medications, previous exposure to biologics, molecular profile) will be obtained and subject, disease, clinical, and trial characteristics that may be associated with a placebo response in clinical and endoscopic disease activity will be identified (Extraction sheet is attached) for induction and maintenance trials.

Statistical analyses will be performed on the data received, using a complete-case analysis. Depending on the severity of missing data, we will attempt to use multiple imputation as a sensitivity analysis. Raw data for end of treatment visits will be collected, as opposed to scores derived by imputation methods (e.g., last observation carried forward, etc). If an imputation method was used to determine the end of treatment score for a subject, the subject should be flagged in the database.

We will be doing either one stage or two stage or both stage analysis IPD meta-analysis. For one stage analysis the trials data will be combined and then analysis will be performed. Two stage analysis will entail obtain summary statistics first, followed by aggregating results from stage one. Summary statistics will be used to describe study and individual participant characteristics for data obtained from the CD and UC trials. Baseline/demographic characteristics, disease activity measures, and improvement in disease activity indices rates will be analyzed using the combined data, separately, for induction, maintenance phases and study-subgroup analyses (i.e., based on previous tumor necrosis factor (TNF) experience and number and class of biologics) of trials. Point estimates and associated 95% confidence intervals [CIs] will be reported.

In the one-stage analysis, generalized linear mixed-effects approach will be used to identify the factors (Baseline/demographic characteristics and disease activity measures) associated with the placebo response/remission rates using the various definitions and the study-subgroups. The final model for each outcome will be based on Bayesian information criterion. Adjusted proportions will be obtained from the final model with independent variables centered.

Project Timeline

Target Analysis Start Date
12/1/21

Estimated Analysis Completion Date
11/30/24

Dissemination and Publication Plan

Plan

We anticipate that the analysis will result in a manuscript in a clinical gastroenterology journal, we also anticipate the sharing of the resulting information through presentation at relevant international conferences (e.g., Digestive Disease Week (DDW), and the European Crohn's and Colitis Organization Congress (ECCO)). The results from this study will have several stakeholders. The immediate target audience are those involved in designing clinical trials (primarily researchers, investigators, and industry). Information gleaned on factors effecting placebo rates could help design studies such that the efficacy of new therapeutics can be realized and lead to new and improved treatment options for the unmet need for these diseases. Please see the important timelines below;

- Project start date: 1 Dec 2021,
- Analysis completion date: 1 June 2023
- Abstract & Manuscript drafted: 1 Oct 2023
- Abstract submitted to congress: 1 Dec 2023 (DDW or ECCO)
- Manuscript submitted for publication: 1 March 2024
- Results reported back to the Vivli: 1 Sept 2024
- Project completion date: 30 Nov 2024

Citations


Statistical Analysis Plan

General Plan

This study is an individual participant (or patient) data (IPD) meta-analysis to investigate factors affecting placebo response and remission rates in inflammatory bowel disease randomized controlled trials (RCTs) while accounting for heterogeneity between trials. IPD will be conducted using data for individual subjects randomized to the placebo group in published phase 2 and 3 induction and maintenance RCTs evaluating the safety and efficacy of biologics and small molecule drugs in moderately to severely active CD and UC. Studies were identified by systematic review of all phase 2 and phase 3 trials from the last 10 years (2010-present). List of variables are attached for the data extraction. IPD (e.g., baseline demographic, disease, and clinical characteristics, concomitant medications, previous exposure to biologics, molecular profile) will be obtained and subject, disease, clinical, and trial characteristics that may be associated with a placebo response in clinical and endoscopic disease activity will be identified (Extraction sheet is attached) for induction and maintenance trials.

Statistical analyses will be performed on the data received, using a complete-case analysis. Depending on the severity of missing data, we will attempt to use multiple imputation as a sensitivity analysis. Raw data for end of treatment visits will be collected, as opposed to scores derived by imputation methods (e.g., last observation carried forward, etc). If an imputation method was used to determine the end of treatment score for a subject, the subject should be flagged in the database.

We will be doing either one stage or two stage or both stage analysis IPD meta-analysis. For one stage analysis the trials data will be combined and then analysis will be performed. Two stage analysis will entail obtain summary statistics first, followed by aggregating results from stage one. Summary statistics will be used to describe study and individual participant characteristics for data obtained from the CD and UC trials. Baseline/demographic characteristics, disease activity measures, and improvement in disease activity indices rates will be analyzed using the combined data, separately, for induction, maintenance phases and study-subgroup analyses (i.e., based on previous tumor necrosis factor (TNF) experience and number and class of biologics) of trials. Point estimates and associated 95% confidence intervals [CIs] will be reported.

In the one-stage analysis, generalized linear mixed-effects approach will be used to identify the factors (Baseline/demographic characteristics and disease activity measures) associated with the placebo response/remission rates using the various definitions and the study-subgroups. The final model for each outcome will be based on Bayesian information criterion. Adjusted proportions will be obtained from the final model with independent variables centered.
In the two-stage analysis, proportions from all studies will be pooled using conventional meta-analysis methods. This data will also be used to investigate how characteristics of studies may affect study aggregate. For meta-regression analyses, Disease activity measures variables and the baseline/demographic characteristics variables will be used as the factors. Mixed-effects meta-regression will be used to assess the effect of each study-level characteristic on placebo rates. Random-effects model will be chosen to account for both between- and within-study variability. Point estimates and associated 95% confidence intervals [CIs] will be reported.

Continuous factors will be centered and unadjusted estimates (95% CIs) for outcome proportions obtained, as well as estimates adjusted by important factors. Estimates will be presented as odds ratios (ORs) with P-values. Factors with P-values less than 0.1 in univariate meta-regression will be selected to multivariable meta-regression analysis.

To combine the results from different platforms the estimates from all studies will be pooled as conventional meta-analysis using two stage approach.

In order to maintain the structure and independence of the studies being requested, each study will be kept as a separate file. When combining the studies into a single dataset for the one-stage analysis, we will create a variable that uniquely identifies each study. A similar approach will be taken for the two-stage analysis after proportions have been calculated for each study.

Countries where analysis will be conducted

Canada

Funding

General

Government Funding
NO

Employment Contracts
NO

Additional Contracts or Consultancies
NO

Commercial Funding
YES

Alimentiv is providing funding in the form of resources to conduct the analysis. Alimentiv is a contract research organization that uses the profits from delivery of commercial services to reinvest in academic research that aligns with its partners shared purpose to accelerate drug discovery.

Other Information

Requested Studies

A Multi-Center, Randomized, Double-blind, Placebo-controlled Study of Adalimumab for the Induction of Clinical Remission in Japanese Subjects With Crohn's Disease
PI:
Sponsor: AbbVie
Study ID: NCT00445939
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: M04-729
Data Contributor: AbbVie
IPD Uploaded: NO

A Multi-Center, Randomized, Double-blind, Placebo-controlled Study of Adalimumab for the Maintenance of Clinical Remission in Japanese Subjects With Crohn's Disease
PI:
Sponsor: AbbVie
Study ID: NCT00445432
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: M06-837
Data Contributor: AbbVie
IPD Uploaded: NO

A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Adalimumab for the Induction and Maintenance of Clinical Remission in Chinese Patients With Moderately to Severely Active Crohn's Disease and Elevated High-Sensitivity C-reactive Protein
PI:
Sponsor: AbbVie
Study ID: NCT02499783
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: M14-233
Data Contributor: AbbVie
IPD Uploaded: NO

A Multicenter, Randomized, Double-blind Placebo-controlled Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction of Clinical Remission in Subjects With Moderately to Severely Active Ulcerative Colitis
PI:
Sponsor: AbbVie
Study ID: NCT00385736
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: M06-826
Data Contributor: AbbVie
IPD Uploaded: NO

A Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction and Maintenance of Clinical Remission in Subjects With Moderately to Severely Active Ulcerative Colitis
PI:
Sponsor: AbbVie
Study ID: NCT00408629
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: M06-827
Data Contributor: AbbVie
IPD Uploaded: NO
A Multi-Center, Randomized, Double-Blind, Placebo-controlled Study of Adalimumab in Japanese Subjects With Moderately to Severely Active Ulcerative Colitis.

PI: 
Sponsor: AbbVie (prior sponsor, Abbott)
Study ID: NCT00853099
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: M10-447
Data Contributor: AbbVie

IPD Uploaded:

A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by MLN0002 in Patients With Moderate to Severe Ulcerative Colitis

PI: Takeda
Sponsor: Takeda
Study ID: NCT00783718
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: C13006
Data Contributor: Takeda

IPD Uploaded:

A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by Vedolizumab (MLN0002) in Patients With Moderate to Severe Crohn's Disease

PI: Takeda
Sponsor: Takeda
Study ID: NCT00783692
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: C13007
Data Contributor: Takeda

IPD Uploaded:

A Phase 3, Randomized, Placebo-Controlled, Double-blind, Multicenter Study of the Induction of Clinical Response and Remission by Vedolizumab in Patients With Moderate to Severe Crohn's Disease

PI: Takeda
Sponsor: Takeda
Study ID: NCT01224171
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: C13011
Data Contributor: Takeda

IPD Uploaded:

Phase III, Multicenter, Randomized, Double-blinded, Placebo-controlled, Parallel-group Study to Examine the Efficacy, Safety, and Pharmacokinetics of Intravenous MLN0002 (300 mg) Infusion in Induction and Maintenance Therapy in Japanese Patients With Moderately or Severely Active Ulcerative Colitis

PI: Takeda
Sponsor: Takeda
Study ID: NCT02039505
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: MLN0002/CCT-101
Data Contributor: Takeda

IPD Uploaded:

Phase III, Multicenter, Randomized, Double-blinded, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Intravenous MLN0002 (300 mg) Infusion in Induction and Maintenance Therapy in Japanese Subjects With Moderate or Severe Crohn's Disease

PI: Takeda
Sponsor: Takeda
Study ID: NCT02038920
IRP/Approver: Wellcome Trust
Data Request ID: 00007288
Sponsor ID: MLN0002/CCT-001
Data Contributor: Takeda

IPD Uploaded:

A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in Subjects With Moderately to Severely Active Ulcerative Colitis

PI: Janssen Research & Development, LLC
Sponsor: Janssen Research & Development, LLC
Study ID: NCT00487539
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Sponsor ID: CR014176
Data Contributor: Johnson & Johnson

IPD Uploaded:

A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in Subjects With Moderately to Severely Active Ulcerative Colitis

PI: Janssen Research & Development, LLC
Sponsor: Janssen Research & Development, LLC
Study ID: NCT00488631
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Sponsor ID: CR014179
Data Contributor: Johnson & Johnson

IPD Uploaded:

A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind, Randomized-withdrawal Study to Evaluate the Safety and Efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in Japanese Subjects With Moderately to Severely Active Ulcerative Colitis

PI: Janssen Pharmaceutical K.K.
Sponsor: Janssen Pharmaceutical K.K.
Study ID: NCT01863771
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Sponsor ID: CR100937
Data Contributor: Johnson & Johnson

IPD Uploaded:

A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Intravenously, in Subjects With Moderately to Severely Active Ulcerative Colitis

PI: Janssen Research & Development, LLC
Sponsor: Janssen Research & Development, LLC
Study ID: NCT00488774
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Sponsor ID: CR014188
Data Contributor: Johnson & Johnson

IPD Uploaded:
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Infliximab in Chinese Subjects With Active Ulcerative Colitis

PI: [Name]
Sponsor: Xian-Janssen Pharmaceutical Ltd.
Study ID: NCT01551290
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Data Contributor: Johnson & Johnson
IPD Uploaded:

A Phase 2b, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Ustekinumab Therapy in Subjects With Moderately to Severely Active Crohn's Disease Previously Treated With TNF Antagonist Therapy

PI: [Name]
Sponsor: Centocor, Inc.
Study ID: NCT00771667
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Sponsor ID: CR015238
Data Contributor: Johnson & Johnson
IPD Uploaded:

A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects With Moderately to Severely Active Crohn's Disease Who Have Failed or Are Intolerant to TNF Antagonist Therapy (UNITI-1)

PI: [Name]
Sponsor: Janssen Research & Development, LLC
Study ID: NCT01369329
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Sponsor ID: CR018415
Data Contributor: Johnson & Johnson
IPD Uploaded:

A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects With Moderately to Severely Active Crohn's Disease (UNITI-2)

PI: [Name]
Sponsor: Janssen Research & Development, LLC
Study ID: NCT01369342
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Sponsor ID: CR018418
Data Contributor: Johnson & Johnson
IPD Uploaded:

A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects With Moderately to Severely Active Crohn's Disease

PI: [Name]
Sponsor: Janssen Research & Development, LLC
Study ID: NCT01369355
IRP/Approver: Johnson & Johnson
Data Request ID: 00007288
Sponsor ID: CR018421
Data Contributor: Johnson & Johnson
IPD Uploaded:

Attached Files