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History of Changes for Study: NCT02407236

A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderat Severely Active Ulcerative Colitis (UNIFI)

Latest version (submitted January 3 2023) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of th
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in green.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 30 2015	None (earliest Version on record)
2	○	○	April 20 2015	Study Status
3	○	○	May 11 2015	Study Status
4	○	○	June 1 2015	Study Status
5	○	○	July 14 2015	Study Status
6	○	○	August 11 2015	Study Status and Contacts/Locations
7	◉	○	September 23 2015	Contacts/Locations and Study Status
8	○	◉	October 16 2015	Recruitment Status, Contacts/Locations and Study Status
9	○	○	November 6 2015	Contacts/Locations and Study Status
10	○	○	November 27 2015	Contacts/Locations and Study Status
11	○	○	December 21 2015	Contacts/Locations and Study Status
12	○	○	January 12 2016	Contacts/Locations and Study Status
13	○	○	February 2 2016	Contacts/Locations and Study Status
14	○	○	February 23 2016	Contacts/Locations and Study Status
15	○	○	March 15 2016	Contacts/Locations and Study Status
16	○	○	April 5 2016	Contacts/Locations and Study Status
17	○	○	April 22 2016	Contacts/Locations and Study Status
18	○	○	May 13 2016	Contacts/Locations and Study Status
19	○	○	June 1 2016	Contacts/Locations and Study Status
20	○	○	June 22 2016	Contacts/Locations and Study Status
21	○	○	July 13 2016	Contacts/Locations and Study Status
22	○	○	August 3 2016	Contacts/Locations and Study Status

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Version	A	B	Submitted Date	Changes
23	○	○	August 24 2016	Contacts/Locations and Study Status
24	○	○	October 14 2016	Contacts/Locations and Study Status
25	○	○	November 12 2016	Contacts/Locations, Study Status and Oversight
26	○	○	December 12 2016	Contacts/Locations and Study Status
27	○	○	February 10 2017	Contacts/Locations and Study Status
28	○	○	March 10 2017	Study Status and Contacts/Locations
29	○	○	March 21 2017	Contacts/Locations and Study Status
30	○	○	April 20 2017	Contacts/Locations, Study Status and Oversight
31	○	○	May 16 2017	Study Status and Contacts/Locations
32	○	○	June 13 2017	Contacts/Locations and Study Status
33	○	○	July 11 2017	Study Status and Contacts/Locations
34	○	○	August 8 2017	Contacts/Locations and Study Status
35	○	○	September 6 2017	Recruitment Status, Contacts/Locations, Study Status and Study Design
36	○	○	November 28 2017	Study Status and Contacts/Locations
37	○	○	February 26 2018	Study Status and Contacts/Locations
38	○	○	March 21 2018	Study Status and Study Design
39	○	○	August 13 2018	Study Status and Study Design
40	○	○	October 3 2018	Study Status
41	○	○	October 31 2018	Study Design and Study Status
42	○	○	November 28 2018	Study Status and Study Design
43	○	○	March 21 2019	Study Status and Study Design
44	○	○	April 18 2019	Study Status and Contacts/Locations
45	○	○	May 16 2019	Study Status and Study Design
46	○	○	June 13 2019	Study Status
47	○	○	August 8 2019	Study Status
48	○	○	August 26 2019	Arms and Interventions and Study Status
49	○	○	October 31 2019	Study Status ▶ Results Submission Events
50	○	○	December 20 2019	Outcome Measures, Study Status, More Information, Document Section, Adverse Events, Baseline Characteristics, Participant Flow and Study Design
51	○	○	January 21 2020	Study Status
52	○	○	February 18 2020	Study Status and Contacts/Locations
53	○	○	March 17 2020	Study Status
54	○	○	April 14 2020	Study Status and Contacts/Locations
55	○	○	May 12 2020	Study Status
56	○	○	July 7 2020	Study Status
57	○	○	September 29 2020	Study Status and Contacts/Locations
58	○	○	October 27 2020	Study Status

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Version	A	B	Submitted Date	Changes
59	○	○	November 24 2020	Study Status
60	○	○	December 22 2020	Contacts/Locations and Study Status
61	○	○	January 19 2021	Study Status
62	○	○	March 16 2021	Study Status
63	○	○	April 12 2021	Study Status
64	○	○	May 11 2021	Study Status
65	○	○	June 7 2021	Study Status
66	○	○	July 6 2021	Study Status
67	○	○	August 3 2021	Contacts/Locations and Study Status
68	○	○	August 31 2021	Study Status
69	○	○	September 28 2021	Study Status
70	○	○	October 26 2021	Study Status
71	○	○	November 23 2021	Study Status
72	○	○	February 2 2022	Recruitment Status and Study Status
73	○	○	August 2 2022	Study Status and Contacts/Locations
74	○	○	November 29 2022	Adverse Events, Participant Flow, Baseline Characteristics, Study Status, Document Section and More Information
75	○	○	January 3 2023	Study Status

Compare Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Compare v6 to v7

Changes (Merged) for Study: NCT02407236
September 23, 2015 (v7) -- October 16, 2015 (v8)

Comp

Changes in: Study Status and Contacts/Locations

☐ **Show only changed modules**

Study Identification

Unique Protocol ID: CR106920

Brief Title: A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (UNIFI)

Official Title: A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy Ustekinumab Induction and Maintenance Therapy in Subjects With Moderately to Severely Active Ulcerative Colitis

Secondary IDs: 2014-005606-38 [EudraCT Number]
CNTO1275UCO3001 [Janssen Research & Development, LLC]

Study Status

Record Verification: ~~September 2015~~ October 2015

Overall Status: ~~Not yet recruiting~~ Recruiting

Study Start: July 2015

Primary Completion: April 2018 [Anticipated]

Study Completion: July 2021 [Anticipated]

First Submitted: March 30, 2015

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First Submitted that Met QC Criteria:	March 30, 2015
First Posted:	April 2, 2015 [Estimate]
Last Update Submitted that Met QC Criteria:	~~September 23, 2015~~ October 16, 2015
Last Update Posted:	~~September 24~~ October 19, 2015 [Estimate]

Sponsor/Collaborators

Sponsor:	Janssen Research & Development, LLC
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	The purpose of this study is to evaluate the efficacy and safety of ustekinumab as intravenous (IV: into the vein) infusion in inductio in participants with moderately to severely active Ulcerative Colitis (UC) and as subcutaneous (SC) administration in maintenance participants with moderately to severely active Ulcerative Colitis (UC) who have demonstrated a clinical response to Induction treat with IV ustekinumab.
Detailed Description:	This is a Phase 3, randomized (assignment of study drug by chance), double-blind (neither the participant or study staff will know tl identity of study drugs), placebo-controlled (placebo is an inactive substance that is compared with a drug to test whether the drug real effect in a clinical trial), parallel-group (a medical research study comparing the response in 2 or more groups of participants re different interventions), multi-center (more than one clinical site will work on a medical research study), protocol of ustekinumab. Th protocol will consist of 2 studies: an Induction study and a Maintenance study with unique endpoints. Screening period will be up to Weeks. Induction study will be at least 8 weeks duration for each participant. Participant with clinical response in the Induction stud be eligible for the Maintenance study. The Maintenance study will be 44 weeks duration. After completion of the maintenance study term extension will follow eligible participants for an additional 3 years. Clinical remission will be evaluated at Week 8 in the Inducti study. Clinical remission among ustekinumab Induction responders will be evaluated at week 44 in the Maintenance study. Particip safety will be monitored throughout.

Conditions

Conditions:	Colitis, Ulcerative Inflammatory Bowel Diseases
Keywords:	Ustekinumab Inflammatory Bowel Diseases (IBD) Colitis, Ulcerative

Study Design

Study Type:	Interventional
Primary Purpose:	Other
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	10
Masking:	Double (Participant, Investigator)
Allocation:	Randomized
Enrollment:	951 [Anticipated]

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Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: Induction Study - Placebo Intravenous (IV) Participants will be randomized to receive single dose of placebo as Intravenous (IV: into the vein) infusion at Week 0. Participants with clinical response at Week 8 will be eligible to enter the Maintenance study, but will not be randomized.	Drug: Placebo IV Placebo will be administered as intravenous infusion.
Experimental: Induction Study - Ustekinumab 130 milligram (mg) IV Participants will be randomized to receive single dose of ustekinumab 130 mg as IV infusion at Week 0. Participants with clinical response at Week 8 will be eligible to enter the Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infus Week 0 or Week 8 in Induction Study.
Experimental: Induction Study - Ustekinumab 6 mg/kg IV Participants will be randomized to receive ustekinumab approximating 6 mg/kg of body weight, as intravenous infusion at Week 0. Participants with clinical response at Week 8 will be eligible to enter the Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infus Week 0 or Week 8 in Induction Study.
Induction Study- Placebo- Nonresponsders at Week 8 Participants without clinical response to placebo at Week 8 will receive a single IV infusion of ustekinumab approximating 6mg/kg along with matching subcutaneous (SC) placebo (to maintain the blind). Participants in clinical response at Week 16 will be eligible to enter Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infus Week 0 or Week 8 in Induction Study.
Induction study-Ustekinumab Nonresponders at Week 8 Participants without clinical response to ustekinumab (130 mg or 6 mg/kg [IV]) at Week 8 will receive a single dose of ustekinumab 90 mg subcutaneously along with matching placebo intravenously (to maintain the blind). Participants in clinical response at Week 16 (that is, delayed responders) will be eligible to enter Maintenance study, but will not be randomized.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Placebo Comparator: Maintenance Study - Placebo Subcutaneous (SC) Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44.	Drug: Placebo SC Placebo will be administered Subcutaneously.
Experimental: Maintenance Study - Ustekinumab 90mg SC every 12 weeks Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive ustekinumab 90 mg subcutaneously every 12 weeks, beginning Week 0 of Maintenance study through Week 44.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Experimental: Maintenance Study - Ustekinumab 90mg SC every 8 weeks (q8w) Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive ustekinumab 90 mg subcutaneously every 8 weeks, beginning Week 0 of Maintenance study through Week 44.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Maintenance Study - Placebo IV - Responder - Placebo SC Participants in clinical response to Induction treatment with IV Placebo will receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44. Participants are not randomized.	Drug: Placebo SC Placebo will be administered Subcutaneously.
Maintenance Study-Delayed Responder-Ustekinumab 90mg SC q8w Participants without clinical response to induction treatment ustekinumab (130 mg or 6 mg/kg [IV]) at Week 8 but in clinical response at Week 16 after receiving Induction Ustekinumab at week 8 (delayed responders) will receive ustekinumab 90 mg subcutaneously every 8 weeks, beginning Week 0 of Maintenance study through Week 44. Participants are not randomized.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.

Outcome Measures

Primary Outcome Measures:

1. Induction Study - Number of Participants With Clinical Remission
   [Time Frame: Week 8]

   The global definition of Clinical remission is defined as Mayo score less than or equal to (<=) 2 points, with no individual subscore than (>) 1, for countries outside the United States (US). For the US, Clinical remission is defined as absolute stool number <=3, a bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity ulcerative colitis. The Mayo score ranges from 0 to 12 points and consists of 4 subscores (stool frequency, rectal bleeding, finding flexible sigmoidoscopy and physician's global assessment), each subscore is graded from 0 to 3 with the higher score indicating r severe disease activity.

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2. Maintenance Study - Number of Participants with Clinical Remission Among Participants in Clinical Response to IV Ustekinumab Induction Treatment
[Time Frame: Week 44]

The global definition of Clinical remission is defined as Mayo score less than or equal to (<=) 2 points, with no individual subscore than (>) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number <=3, a bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity ulcerative colitis. The Mayo score ranges from 0 to 12 points and consists of 4 subscores (stool frequency, rectal bleeding, finding flexible sigmoidoscopy and physician's global assessment), each subscore is graded from 0 to 3 with the higher score indicating r severe disease activity.

Secondary Outcome Measures:

1. Induction Study - Number of Participants with Clinical Response
[Time Frame: Week 8]

Clinical response is defined as a decreased from Induction baseline in the Mayo score by greater than or equal to (>=) 30 percen and >=3 points, with either a decrease from induction baseline in the rectal bleeding subscore >=1 or rectal bleeding subscore = (

2. Induction Study - Number of Participants With Endoscopic Healing
[Time Frame: Week 8]

Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It will be defined as Mayo endoscopic subscore 1.

3. Induction Study - Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Score
[Time Frame: Week 8]

The IBDQ is a 32-item questionnaire for participants with Inflammatory Bowel Disease (IBD) that will be used to evaluate the dise specific health-related quality of life across 4 dimensional scores: bowel (loose stools, abdominal pain), systemic (fatigue, altered pattern), social (work attendance, need to cancel social events), and emotional (anger, depression, irritability). The total score ran from 32 to 224 with higher scores indicating better quality of life.

4. Maintenance Study - Number of Participants with Clinical Response Among Participants in Clinical Response to IV Ustekinumab Induction Treatment
[Time Frame: Through Week 44]

Clinical response is defined as a decreased from Induction baseline in the Mayo score by greater than or equal to (>=) 30 percen and >=3 points, with either a decrease from Induction baseline in the rectal bleeding subscore >=1 or rectal bleeding subscore = (

5. Maintenance Study - Number of Participants with Endoscopic Healing Among Participants in Clinical Response to IV Ustekinumal Induction Treatment
[Time Frame: Week 44]

Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It will be defined as Mayo endoscopic subscore 1.

6. Maintenance Study - Number of Participants with Clinical Remission Among those who Achieved Clinical Remission at Maintenar Study Baseline
[Time Frame: Through Week 44]

The global definition of Clinical remission is defined as Mayo score less than or equal to (<=) 2 points, with no individual subscore than (>) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number <=3, a bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity ulcerative colitis.

7. Maintenance Study - Number of Participants with Clinical Remission and not Receiving Concomitant Corticosteroids Among those Receiving Concomitant Corticosteroids at Maintenance Baseline
[Time Frame: Week 44]

The global definition of Clinical remission is defined as Mayo score less than or equal to (<=) 2 points, with no individual subscore than (>) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number <=3, a bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity ulcerative colitis.

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Has a clinical diagnosis of Ulcerative Colitis (UC) at least 3 months before Screening
- Has moderately to severely active UC, defined as a Baseline (Week 0) Mayo score of 6 to 12, including a Screening endosco subscore of the Mayo score greater than or equal to (>=) 2 as determined by a central reading of the video endoscopy
- Have failed biologic therapy, that is, have received treatment with 1 or more tumour necrosis factor (TNF) antagonists or vedolizumab at a dose approved for the treatment of UC, and have a documented history of failure to respond to or tolerate s treatment; OR Be naïve to biologic therapy (TNF antagonists or vedolizumab) or have received biologic therapy but have not demonstrated a history of failure to respond to, or tolerate, a biologic therapy and have a prior or current UC medication histo includes at least 1 of the following: a. Inadequate response to or failure to tolerate current treatment with oral corticosteroids immunomodulators (6-mercaptopurine [6-MP] or azathioprine [AZA]) OR b. History of failure to respond to, or tolerate, at leas the following therapies: oral or IV corticosteroids or immunomodulators (6-MP or AZA) OR c. History of corticosteroid depend (that is, an inability to successfully taper corticosteroids without a return of the symptoms of UC)
- Before the first administration of study agent, the following conditions must be met: vedolizumab must have been discontinue least 4 months and anti-tumor necrosis factors (TNFs) for at least 8 weeks

Exclusion Criteria:

- Has severe extensive colitis and is at imminent risk of colectomy
- Has UC limited to the rectum only or to < 20 centimeters (cm) of the colon
- Presence of a stoma or history of a fistula
- Participants with history of extensive colonic resection (for example, less than 30 cm of colon remaining) that would prevent adequate evaluation of the effect of study agent on clinical disease activity
- Participants with history of colonic mucosal dysplasia. Participants will not be excluded from the study because of a patholog finding of "indefinite dysplasia with reactive atypia"

Contacts/Locations

Central Contact Person: Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions:
Email: JNJ.CT@sylogent.com

Study Officials: Janssen Research & Development, LLC Clinical Trial
Study Director
Janssen Research & Development, LLC

Locations: **United States, Alabama**

[Not yet recruiting]
Birmingham, Alabama, United States

United States, California

[Not yet recruiting]
La Mirada, California, United States

[Not yet recruiting]
Los Angeles, California, United States

[Recruiting]
Newport Bech, California, United States

[Recruiting]
Torrance, California, United States

[Not yet recruiting]
Vallejo, California, United States

United States, District of Columbia

[Not yet recruiting]
Washington, District of Columbia, United States

United States, Florida

[Not yet recruiting]
Atlantis, Florida, United States

[Not yet recruiting]
Gainesville, Florida, United States

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[Recruiting]
Largo, Florida, United States

[Not yet recruiting]
Miami, Florida, United States

[Recruiting]
Port Orange, Florida, United States

[Not yet recruiting]
Tampa, Florida, United States

[Not yet recruiting]
Winter Park, Florida, United States

[Recruiting]
Zephyrhills, Florida, United States

United States, Georgia

[Not yet recruiting]
Atlanta, Georgia, United States

[Not yet recruiting]
Decatur, Georgia, United States

[Not yet recruiting]
Macon, Georgia, United States

[Recruiting]
Suwanee, Georgia, United States

United States, Idaho

[Recruiting]
Idaho Falls, Idaho, United States

United States, Illinois

[Not yet recruiting]
Chicago, Illinois, United States

[Not yet recruiting]
Evanston, Illinois, United States

[Not yet recruiting]
Maywood, Illinois, United States

United States, Kansas

[Recruiting]
Pratt, Kansas, United States

United States, Kentucky

[Recruiting]
Crestview Hills, Kentucky, United States

[Not yet recruiting]
Lexington, Kentucky, United States

[Not yet recruiting]
Louisville, Kentucky, United States

United States, Louisiana

[Recruiting]
Shreveport, Louisiana, United States

United States, Maryland

[Not yet recruiting]
Columbia, Maryland, United States

United States, Massachusetts

[Not yet recruiting]
Boston, Massachusetts, United States

United States, Michigan

[Not yet recruiting]
Ann Arbor, Michigan, United States

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[Recruiting]
Chesterfield, Michigan, United States

[Not yet recruiting]
Urbana, Michigan, United States

[Recruiting]
Ypsilanti, Michigan, United States

United States, Minnesota

[Not yet recruiting]
Rochester, Minnesota, United States

United States, New Jersey

[Recruiting]
Marlton, New Jersey, United States

United States, New York

[Not yet recruiting]
Albany, New York, United States

[Not yet recruiting]
Bronx, New York, United States

[Not yet recruiting]
Brooklyn, New York, United States

[Not yet recruiting]
Mineola, New York, United States

[Not yet recruiting]
New York, New York, United States

[Recruiting]
Poughkeepsie, New York, United States

[Not yet recruiting]
Rochester, New York, United States

[Not yet recruiting]
Stony Brook, New York, United States

United States, Ohio

[Not yet recruiting]
Cincinnati, Ohio, United States

[Recruiting]
Mentor, Ohio, United States

United States, Oregon

[Not yet recruiting]
Portland, Oregon, United States

United States, Pennsylvania

[Recruiting]
Doylestown, Pennsylvania, United States

[Not yet recruiting]
Hershey, Pennsylvania, United States

[Not yet recruiting]
Philadelphia, Pennsylvania, United States

United States, Tennessee

[Not yet recruiting]
Germantown, Tennessee, United States

[Not yet recruiting]
Nashville, Tennessee, United States

[Recruiting]
Nashville, Tennessee, United States

United States, Texas

[Not yet recruiting]
Bellaire, Texas, United States

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[Not yet recruiting]
Dallas, Texas, United States

[Not yet recruiting]
Houston, Texas, United States

[Not yet recruiting]
Killeen, Texas, United States

[Withdrawn]
San Antonio, Texas, United States

[Recruiting]
San Antonio, Texas, United States

[Not yet recruiting]
Tyler, Texas, United States

United States, Utah

[Not yet recruiting]
Salt Lake City, Utah, United States

[Not yet recruiting]
West Jordan, Utah, United States

United States, Virginia

[Recruiting]
Chesapeake, Virginia, United States

[Not yet recruiting]
Fairfax, Virginia, United States

[Not yet recruiting]
Roanoke, Virginia, United States

United States, Washington

[Recruiting]
Seattle, Washington, United States

[Not yet recruiting]
Seattle, Washington, United States

Australia

[Not yet recruiting]
Bedford, Australia

[Not yet recruiting]
Central Queensland M C, Australia

[Not yet recruiting]
Clayton, Australia

[Not yet recruiting]
Concord N/A, Australia

[Recruiting]
Fitzroy, Australia

[Recruiting]
Five Dock, Australia

[Not yet recruiting]
Garran, Australia

[Not yet recruiting]
Heidelberg, Australia

[Not yet recruiting]
Liverpool, Australia

[Not yet recruiting]
Melbourne, Australia

[Not yet recruiting]
South Brisbane, Australia

Austria

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[Not yet recruiting]
Salzburg, Austria

[Not yet recruiting]
St Veit An Der Glan, Austria

[Withdrawn]
Wien, Austria

[Not yet recruiting]
Wien, Austria

Belgium

[Withdrawn]
Antwerpen, Belgium

[Not yet recruiting]
Gent, Belgium

[Not yet recruiting]
Kortrijk, Belgium

[Not yet recruiting]
Leuven, Belgium

[Not yet recruiting]
Liège, Belgium

Bulgaria

[Not yet recruiting]
Sofia, Bulgaria

Canada, British Columbia

[Not yet recruiting]
Victoria, British Columbia, Canada

Canada, Manitoba

[Not yet recruiting]
Brandon, Manitoba, Canada

[Not yet recruiting]
Winnipeg, Manitoba, Canada

Canada, Ontario

[Not yet recruiting]
London, Ontario, Canada

[Not yet recruiting]
Sudbury, Ontario, Canada

Canada, Quebec

[Not yet recruiting]
Montreal, Quebec, Canada

Czech Republic

[Not yet recruiting]
Hradec Kralove, Czech Republic

[Not yet recruiting]
Plzen, Czech Republic

[Not yet recruiting]
Prague 4, Czech Republic

[Not yet recruiting]
Praha 5, Czech Republic

[Not yet recruiting]
Praha 7, Czech Republic

[Not yet recruiting]
Praha 9, Czech Republic

Denmark

[Not yet recruiting]
Aarhus, Denmark

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[Not yet recruiting]
Odense, Denmark

France

[Not yet recruiting]
Amiens, France

[Not yet recruiting]
Bordeaux, France

[Not yet recruiting]
Lille, France

[Not yet recruiting]
Marseille, France

[Not yet recruiting]
Pierre-Benite, France

[Not yet recruiting]
Rennes, France

[Not yet recruiting]
Saint-Etienne, France

Germany

[Not yet recruiting]
Dresden, Germany

[Not yet recruiting]
Mannheim, Germany

Hungary

[Not yet recruiting]
Balatonfüred, Hungary

[Not yet recruiting]
Budapest, Hungary

[Not yet recruiting]
Békéscsaba, Hungary

[Not yet recruiting]
Debrecen, Hungary

[Recruiting]
Debrecen, Hungary

[Not yet recruiting]
Miskolc, Hungary

[Not yet recruiting]
Mosonmagyarovar, Hungary

[Not yet recruiting]
Szekszárd, Hungary

[Not yet recruiting]
Szombathely, Hungary

[Not yet recruiting]
Székesfehérvár, Hungary

[Not yet recruiting]
Vac, Hungary

Israel

[Not yet recruiting]
Afula, Israel

[Not yet recruiting]
Beersheba, Israel

[Not yet recruiting]
Holon, Israel

[Not yet recruiting]
Jerusalem, Israel

[Not yet recruiting]
Nahariya, Israel

[Not yet recruiting]
Tel Aviv, Israel

Japan

[Recruiting]
Chikushinoshi, Japan

[Not yet recruiting]
Fujiidera, Japan

[Not yet recruiting]
Higashi-Ibaraki, Japan

[Not yet recruiting]
Hirosaki, Japan

[Not yet recruiting]
Hiroshima, Japan

[Not yet recruiting]
Iwate, Japan

[Not yet recruiting]
Izumo, Japan

[Not yet recruiting]
Kagawa, Japan

[Not yet recruiting]
Kagoshima, Japan

[Not yet recruiting]
Kahoku, Japan

[Not yet recruiting]
Kochi, Japan

[Not yet recruiting]
Kurume, Japan

[Not yet recruiting]
Kyoto, Japan

[Not yet recruiting]
Nagasaki, Japan

[Not yet recruiting]
Nara, Japan

[Not yet recruiting]
Nishinomiya, Japan

[Not yet recruiting]
Oita, Japan

[Not yet recruiting]
Osaka, Japan

[Not yet recruiting]
Saga-Ken, Japan

[Not yet recruiting]
Saitama, Japan

[Not yet recruiting]
Sakura, Japan

[Recruiting]
Sapporo, Japan

[Not yet recruiting]
Sendai, Japan

[Not yet recruiting]
Shizuoka, Japan

[Not yet recruiting]
Sunto-Gun, Japan

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[Not yet recruiting]
Tokyo, Japan

[Withdrawn]
Tokyo, Japan

[Not yet recruiting]
Toyota, Japan

[Not yet recruiting]
Tsu, Japan

[Not yet recruiting]
Wakayama, Japan

[Not yet recruiting]
Yamanashi, Japan

Korea, Republic of

[Not yet recruiting]
Daegu, Korea, Republic of

[Not yet recruiting]
Seoul, Korea, Republic of

Netherlands

[Not yet recruiting]
Amsterdam, Netherlands

[Not yet recruiting]
Maastricht, Netherlands

New Zealand

[Not yet recruiting]
Auckland, New Zealand

[Not yet recruiting]
Christchurch, New Zealand

[Not yet recruiting]
Dunedin, New Zealand

[Not yet recruiting]
Lower Hutt, New Zealand

[Not yet recruiting]
Milford, New Zealand

Romania

[Not yet recruiting]
Bucuresti, Romania

[Not yet recruiting]
Oradea, Romania

[Not yet recruiting]
Romania, Romania

[Not yet recruiting]
Timisoara, Romania

Russian Federation

[Not yet recruiting]
Irkutsk, Russian Federation

[Not yet recruiting]
Moscow, Russian Federation

[Not yet recruiting]
Novosibirsk, Russian Federation

[Not yet recruiting]
Rostov-On-Don, Russian Federation

[Not yet recruiting]
Ryazan, Russian Federation

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[Not yet recruiting]
Saint Petersburg, Russian Federation

[Not yet recruiting]
St Petersburg, Russian Federation

Slovakia

[Not yet recruiting]
Presov, Slovakia

[Not yet recruiting]
Ruzomberok, Slovakia

South Africa

[Not yet recruiting]
Cape Town, South Africa

[Not yet recruiting]
Claremont, South Africa

[Not yet recruiting]
Durban, South Africa

[Not yet recruiting]
Soweto, South Africa

Ukraine

[Not yet recruiting]
Kyiv, Ukraine

United Kingdom

[Not yet recruiting]
Cambridge, United Kingdom

[Not yet recruiting]
Coventry, United Kingdom

[Not yet recruiting]
Doncaster, United Kingdom

[Not yet recruiting]
Edinburgh, United Kingdom

[Not yet recruiting]
Liverpool, United Kingdom

[Not yet recruiting]
London, United Kingdom

[Not yet recruiting]
Norwich, United Kingdom

[Not yet recruiting]
Salford, United Kingdom

[Not yet recruiting]
Southampton, United Kingdom

[Not yet recruiting]
Sutton In Ashfield, United Kingdom

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