The Availability of Data from Clinical Trials: The Case of Crohn's Disease

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Acknowledgements

Introduction

The United States spent an estimated $540 billion on prescription drugs and medical equipment in 2017 ($450 billion on prescription drugs alone).[1] Clinical trials which evaluate prescription drugs and new devices prior to their entrance on the market are usually financed and sometimes even carried out by the company holding the intellectual property rights to the technology in question. This is problematic for several reasons. There is an obvious incentive to conceal or underreport trial data which could be harmful to a drug's sales potential or reputation.

It has been estimated that up to half of all clinical trials never have their results published. Similarly, positive results are twice as likely to be published (and published promptly) than trials with negative results.[2] Ross et al. (2009) found that the results of trials primarily sponsored by industry are less likely to be published than those sponsored by nonindustry or nongovernment groups.[3] Bourgeois et al. (2010) examined drug trials registered in the website ClinicalTrials.gov and found that industry-funded trials reported positive outcomes in 85.4 percent of publications compared with 50.0 percent for government-funded trials.[4] Naturally, there are obvious concerns regarding conflicts of interest when safety trials are funded and carried out by industry.[5]

ClinicalTrials.gov is a publicly available internet-based resource maintained by the National Library of Medicine at the National Institutes of Health (NIH). Generally speaking, any clinical trial studying an interventional therapy or a device regulated by the Food and Drug Administration (FDA) must register with the website. Registrants are required to disclose certain information such as sponsoring parties, study design, and eligibility criteria, among other descriptors. However, they are not required to disclose details of study participants prior to intervention or their respective outcomes following intervention.[6]

Our study seeks to briefly characterize the data made available through ClinicalTrials.gov in order to better understand what information is available to prescribers and investigators not involved in the marketing of the drug or device. In doing so, we underscore the potentially enormous value of publicly funding clinical trials in terms of both patient safety and economic cost.[7]

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1   Bureau of Economic Analysis (2018).
2   Health Affairs (2016).
3   Ross et al. (2009).
4   Bourgeois et al. (2010).
5   Bekelman et al. (2003).
6   ClinicialTrials.gov (2018).
7   Baker (2008).

Methods

Using the advanced search tool available at ClinicalTrials.gov, we arbitrarily chose Crohn's Disease (CD) as a disease process for which there would be therapeutic investigations. We indexed only those trials that were completed and "had results" to report. For the sake of simplicity, we filtered through only trials involving adults and based in the United States.

Using these parameters, we identified all completed trials involving therapies for adults with CD. We then examined each trial to assess the data made available by the study investigators. We determined what baseline patient characteristics were reported, the primary outcome being assessed, the number of participants involved, and the primary funding source for each study. This information was then compiled and further analyzed and quantified.

After reviewing the data available at ClinicalTrials.gov, we then searched through the academic literature to see which of these trials led to published articles. We found 32 journal articles reporting results for some of the trials. In addition to examining the articles, we also contacted the lead authors to see if they would make their data available for further analysis.

Results

We identified 53 trials indexed in ClinicalTrials.gov involving drugs or devices for CD. **Table 1** summarizes each trial and the data made available by the investigators. The start dates of trials indexed ranged from 2004 to 2014. Zero out of 53 trials examined reported any data about individual patients. Patient data was universally reported as aggregate characteristics (e.g., mean age with standard deviation, gender split). 43 out of 53 trials examined were funded in part or completely by industry.

Of the 53 trials listed in ClinicalTrials.gov, 32 of them led to published journal articles as of January 2018. **Table 2** summarizes the data available in these articles. While most of the studies gave aggregate data for baseline characteristics (e.g., the number of men and women in the study, race, weight, etc.) only five of the studies gave a breakdown of outcomes by baseline characteristics. The other studies did not indicate, for example, whether the treatment was more effective for men than women or for younger people than older people. One of the studies did provide a full set of baseline characteristics for each participant and their outcomes.

Our efforts to contact the authors to see if they would make the data available for further analysis were mostly unsuccessful. The authors of six of the 32 articles responded. Three indicated that the data were not under their control and could only be shared with permission of the company that had sponsored the research. One author declined to share the data because they were concerned "[…]would potentially open us up to faulty analyses and the emergence or publication of false results." Only one of the six authors indicated they could make de-identified data available, with the de-identification including the removal of birth dates, which presumably would preclude any analysis based on the ages of participants. It is worth pointing out that several of these studies are nearly a decade old, so it is possible that a more timely effort to contact the authors would have proven more successful.

Discussion

The lack of transparency surrounding drug safety and efficacy data is an enormous loss to potential users of data, either clinicians or other investigators. The researchers conducting the trial obviously have extensive data on the baseline characteristics of the trial participants and know the outcomes for each participant. These data would make it possible to determine whether the effectiveness and safety of a drug or device differed between men and women, whether there were differences by age, weight, or various health conditions.

Clinicians could benefit from having access to this information when determining the best course of treatment for their patients. It may well be the case that a specific drug has better overall results than another drug, but is less effective for particular groups or is more likely to have negative side effects for some groups. With current policy, this information may come out through voluntary disclosures or required warnings from the FDA. However, only a small fraction of the information from these trials is ever likely to be available to independent analysts.

In many cases, the researchers conducting the trial may themselves not recognize important differences in outcomes simply because they did not fully analyze the results. Making the data on outcomes available to other researchers would allow them to independently analyze the results to uncover significant differences in outcomes across groups. This would be useful data even in trials with negative results, since there may still be information suggesting either potential uses for some subset of the population, or greater risks that may serve as a warning against a particular pattern of treatment for certain demographic groups.

Since the researchers conducting a trial already have data on outcome and baseline characteristics, the cost of making them publicly available on the internet should be quite modest. There are issues related to preserving patient privacy, but it should not be difficult to anonymize the data so that instances where it could be used to identify specific patients would be extremely rare.[8]

As a policy matter, the government could require full disclosure of test results for any study receiving any form of government funding. This would mean that where the NIH or other government agency helped to support a trial, or if the trial received the benefit of the Orphan Drug tax credit, the results would have to be fully disclosed on the internet in a timely manner. The government could also take the lead and make these disclosures for the studies it conducts itself. Ideally, full disclosure would become the norm so that even studies that are financed entirely by the private sector would follow this practice.

The aggregate knowledge and insight gained following discussion, criticism, and analysis by unbiased investigators would facilitate safer prescribing practices and perhaps lead to the development of better drugs. The free exchange of data and results is, in fact, how modern science works. There is already substantial evidence of the benefits from more open access to clinical trial data. For example, the Early Breast Cancer Trialists' Collaborative Group was granted access to individual patient data for 10,801 women in 17 different trials and subsequently published a subgroup analysis for the benefit of breast cancer patients worldwide.[9] This subgroup analysis conducted by the group found that benefits from chemotherapy are most effective in breast cancer patients under 50 years old.[10] Furthermore, it led to the development of improved and minimally invasive surgery techniques.[11]

There has been some pressure on drug companies in recent years to anonymize and de-identify patient-level datasets for outside investigators who request them.[12] However, there is no requirement that they release these data. As this study suggests, and considering the paucity of information available on ClinicalTrials.gov or in published journal articles, the incentive to conceal results remains strong. It would be desirable to have measures that led to greater disclosure of results. The costs of additional disclosure should be trivial. The potential health benefits are enormous.

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8   Sadan (2001).
9   Darby et al. (2011).
10   Darby et al. (2005).
11   Charalampoudis and Karakatsanis (2018).
12   Tucker et al. (2016).

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Tables

TABLE 1

Crohn's Disease Trials Listed on Clinicaltrials.gov								
Study	NCT	Attributes Reported	Primary Outcome	Patient-Specific Data	Sample Size	Year	Funding Source	Funding Type
PillCam® Platform With the PillCam Crohn's Disease Capsule	01631435	Age, Gender	Per-subject diagnostic yield of Pill Cam compared to ileocolonoscopy	None	66	2012	Given Imaging Ltd	Industry
Infliximab for the Prevention of Recurrent Crohn's Disease After Surgery	00688636	Age, Gender	Endoscopic recurrence at one year	None	24	2005	University of Pittsburgh + Centocor	Industry/Academic
Human Anti-TNF Monoclonal Antibody Adalimumab in Canadian Subjects With Moderate to Severe Crohn's Disease (ACCESS)	00427921	Age, Gender, Alcohol, Nicotine, CRP, Weight, Presence of Fistula, Duration of Crohn's Disease	Fistula count mean change from baseline	None	304	2007	Abbott	Industry
Bone Health in Pediatric Crohn's Disease: A Low Magnitude Mechanical Stimulus Trial	00364130	Age, Gender	Change in tibial bone mineral density	None	138	2007	Children's Hospital of Philadelphia, NIDDK	Federal/Academic
Ciprofloxacin for the Prevention of Postoperative Endoscopic Recurrence in Crohn's Disease	00609973	Age, Gender	Safety and tolerability of ciprofloxacin	None	33	2008	UNC, NIDDK, Crohn's and Colitis Foundation	Federal/Academic/Private
The Effects of Naltrexone on Active Crohn's Disease	00663117	Age, Gender, CDAI	Decline in CDAI	None	40	2006	Penn State University, NIDDK, Broad Foundation	Federal/Academic/Private
Evaluation of a PillCam Colon Bowel Preparation Regimen in Crohn's Disease Patients	01576120	Age, Gender	Effectiveness of Pillcam	None	40	2012	Given Imaging Ltd	Industry
Tumor Necrosis Factor Decreases Vitamin D Dependant Calcium Absorption	00427804	Age, Gender	Intestinal absorption of calcium	None	9	2007	V.A. Atlanta + Emory University	Federal/Academic
Trial of Growth Hormone Therapy in Pediatric Crohn's Disease	00109473	Age, Gender	Crohn's Disease Histologic Severity Index	None	20	2005	Children's Hospital Medical Center of Cincinatti + Genentech	Industry/Academic
Endoscopic Ultrasound (EUS) Guided Treatment With Humira for Crohn's Perianal Fistulas	00517296	Age, Gender	Number of patients with fistula healing	None	20	2008	Vanderbilt University	Academic
Use of Oral Probiotics to Reduce Urinary Oxalate Excretion	00587041	Age, Gender, Total Kidney Stones Passed	Urinary calcium oxalate	None	40	2006	NIH + Mayo Clinic	Federal/Academic
Telemedicine To Provide Inflammatory Bowel Disease Outpatient Care	01296841	Age, Gender	Patient clinical experience	None	34	2009	V.A. Palo Alto	Federal
Patient Attitudes and Preferences for Outcomes of Inflammatory Bowel Disease Therapeutics	02316678	Age, Gender	Mortality	None	9573	2014	University of Pennsylvania, Crohn's and Colitis Foundation, University of Alabama at Birmingham, Duke University, Patient-Centered Outcomes Research Institute	Academic/Private
Anal Human Papillomavirus in Inflammatory Bowel Disease Study	01364896	Age, Gender, Number with Crohn's Disease, Number with Ulcerative Colitis, Number with Indeterminate Colitis	Presence of HPV	None	46	2011	University of Pittsburgh, Merck	Industry/Academic
Bacteriotherapy in Pediatric Inflammatory Bowel Disease	01757964	Age, Gender	UCAI/CDAI	None	13	2012	Seattle Children's Hospital	Academic
Safety and Tolerability of Single Doses Oral CNDO 201 Trichuris Suis Ova in Patients With Crohn's Disease	01434693	Age, Gender	Incidence of Adverse Events	None	36	2011	Coronado Biosciences, Inc.	Industry
Open Label Study for Adults With Pyoderma Gangrenosum and Inflammatory Bowel Disease	00791557	Age, Gender	Efficacy of Infliximab Therapy	None	2	2008	University Hospitals Cleveland Medical Center, Centocor, Inc	Industry/Academic
Efficacy and Safety of Trichuris Suis Ova (TSO) as Compared to Placebo	01576471	Age, Gender, Ethnicity, Race	CDAI	None	250	2012	Coronado Biosciences, Inc.	Industry

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Study	NCT	Attributes Reported	Primary Outcome	Patient-Specific Data	Sample Size	Year	Funding Source	Funding Type
Study for the Treatment of Crohn's Disease With Adacolumn	00162942	Age, Gender, Race, Alcohol, Smoking, Baseline CDAI, Height, Weight, # of Flares in past 12 months	Clinical Remission	None	235	2005	Otsuka America Pharmaceutical	Industry
Study To Test Whether PF-00547659 Is Safe And Improves Disease Symptoms In Patients With Crohn's Disease	01276509	Age, Gender	CDAI	None	265	2011	Shire	Industry
Certolizumab in Crohn's Disease Patients With Loss of Response or Intolerance to Infliximab	00308581	Age, Gender, Region of Enrollment	CDAI	None	539	2006	UCB Pharma	Industry
Vitamin D Supplementation in Crohn's Patients	00742781	Age, Gender	CDAI, VitD level	None	21	2009	Penn State University	Academic
Examining the Long Term Safety, Efficacy, and Corticosteroid-sparing Effect of Certolizumab Pegol in Crohn's Disease	00356408	Age, Gender, Region of Enrollment	Incidence of Adverse Events	None	106	2007	UCB Pharma	Industry
Follow-up to Welcome Study C87042 [NCT00308581] Examining Certolizumab Pegol (CDP870) in Subjects With Crohn's Disease	00333788	Age, Gender, Region of Enrollment	Incidence of Adverse Events	None	233	2006	UCB Pharma	Industry
Study To Assess The Efficacy And Safety Of PF-04236921 In Subjects With Crohn's Disease Who Failed Anti-TNF Therapy	01287897 A	Age, Gender	CDAI	None	250	2011	Pfizer	Industry
Trial Comparing Infliximab and Infliximab and Azathioprine in the Treatment of Patients With Crohn's Disease naive to Both Immunomodulators and Biologic Therapy (Study of Biologic and Immunomodulator Naive Patients in Chrohn's Disease: SONIC	00094458	Age, Gender, Region of Enrollment	Percentage of patients with corticosteroid-free remission	None	508	2005	Centocor	Industry
A Study of the Safety and Efficacy of Ustekinumab (CNTO 1275) in Participants With Crohn's Disease	00265122	Age, Gender	Number of patients with clinical response at Week 8	None	131	2004	Centocor	Industry
A Study to Evaluate Safety of Long Term Therapy of Certolizumab Pegol Patients With Crohn's Disease	00552344	Age, Gender	Percentage of patients with at least one adverse event	None	402	2008	UCB Pharma	Industry
A Study to Investigate the Efficacy and Safety of GSK1605786A in the Treatment of Subjects With Moderately-to-Severely Active Crohn's Disease	01277666	Age, Gender, Race	CDAI	None	608	2010	GlaxoSmithKline	Industry
Study to Evaluate Efficacy and Safety of Certolizumab Pegol for Induction of Remission in Patients With Crohn's Disease	00552058	Age, Gender, Region of Enrollment	Clinical Remission at Week 6	None	439	2008	UCB Pharma	Industry
Evaluation of Capsule Endoscopy in Patients With Suspected Crohn's Disease	00487396	Age, Gender, Region of Enrollment	Number of positive findings suggestive of CD	None	98	2007	Given Imaging (Ltd)	Industry
Remission in Subjects With Crohn's Disease, 1 Year Phase	00055497	Age, Gender	Remission at Week 56	None	276	2002	Abbott	Industry
A Open-Label Study Of CP-690,550 As Long-Term Therapy (48 Weeks) In Subjects With Crohn's Disease	01470599	Age, Gender	Adjudicated adverse events	None	150	2012	Pfizer	Industry
Remission in Subjects With Crohn's Disease, Open Label Extension	01070303	Age, Gender	Number achieving clinical remission	None	177	2012	Abbott	Industry
Study of Vedolizumab in Patients With Moderate to Severe Crohn's Disease	01224171	Age less than/greater than 35, Age less/greater than 65, ethnicity, race, weight, BMI, region, duration of CD, CDAI, CRP, calprotectin, disease location, smoking, fistulization, presence of external manifestations	Number of patients in clinical remission	None	416	2010	Millenium Pharmaceuticals	Industry
Study of Vedolizumab (MLN0002) in Patients With Moderate to Severe Crohn's Disease	00783692	Age less than/greater than 35, Age less/greater than 65, ethnicity, race, weight, BMI, region, duration of CD, CDAI, CRP, calprotectin, disease location, smoking, fistulization, presence of external manifestations	Clinical remission at Week 6	None	1116	2008	Millenium Pharmaceuticals	Industry
Long-term Safety and Tolerability Study of Adalimumab in Subjects With Crohn's Disease	00195715	Age, gender, region of Enrollment	Percentage achieving clinical remission	None	777	2004	Abbott	Industry
A Study to Investigate the Safety and Efficacy of CP-690,550 in Patients With Moderate to Severe Crohn's Disease	00615199	Age, Gender	Clinical response at Week 4	None	139	2008	Pfizer	Industry

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Study	NCT	Attributes Reported	Primary Outcome	Patient-Specific Data	Sample Size	Year	Funding Source	Funding Type
A Study To Investigate Safety And Efficacy Of CP-690,550 For Induction Therapy In Subjects With Moderate To Severe Crohn's Disease	01393626	Age, Gender	CDAI	None	280	2011	Pfizer	Industry
Effects of Adalimumab on Mucosal Healing in Subjects With Crohn's Disease Involving the Colon	00348283	Age, gender, region of Enrollment	Number of subjects without mucosal ulceration at 12 weeks	None	135	2006	Abbott	Industry
A Study of Safety and Effectiveness of Ustekinumab in Patients With Moderate to Severe Active Crohn's Disease Who Have Been Previously Treated With Anti-TNF Therapy	00771667	Age, gender	Clinical response at week 6	None	526	2006	Centocor	Industry
A follow-on Safety Study of CDP870 in Subjects With Crohn's Disease (CD) Who Have Completed a 26- week Double Blind Study CDP870-031 [NCT00152490] or CDP870-032 [NCT00152425]	00160524	Age, gender, region of Enrollment	Percentage of subjects with at least one adverse event	None	596	2004	UCB Pharma	Industry
A follow-on Safety Study in Subjects With Crohn's Disease Who Have Previously Been Withdrawn From the Double-blind Study CDP870-031 [NCT00152490] or CDP870-032 [NCT00152425] Due to an Exacerbation of Crohn's Disease	00160706	Age, gender, region of Enrollment	Percentage of subjects with at least one adverse event	None	310	2004	UCB Pharma	Industry
A Study To Monitor Long-Term Treatment With PF-00547659	01298492	Age, gender	Percentage of subjects with adverse event	None	268	2011	Shire	Industry
The Safety And Efficacy Of Maintenance Therapy With CP-690,550	01393899	Age, gender	CDAI	None	180	2012	Pfizer	Industry
Centocor Microarray Study of Patients	00462072	Age, gender	Disease activity score	None	31	2007	Centocor + University of Rochester	Industry/Academic
A Study to Evaluate the Safety and Efficacy of Ustekinumab in Patients With Moderately to Severely Active Crohn's Disease Who Have Failed or Are Intolerant to Tumor Necrosis Factor (TNF) Antagonist Therapy (UNITI-1)	01369329	Age, gender, region of enrollment	Clinical response at week 6	None	769	2011	Janssen	Industry
A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Patients With Moderately to Severely Active Crohn's Disease (UNITI-2)	01369342	Age, gender, region of enrollment	Clinical response at week 6	None	640	2011	Janssen	Industry
Monitoring Disease Activity Using Video Capsule Endoscopy (VCE) in Crohn's Disease (CD) Subjects	01942720	Age <18, Age between 16 and 85, age > 85, gender	Mucosal change in video capsule endoscopy	None	74	2013	Medtronic	Industry
B0151005 Open-Label Extension Study	01345318	Age, gender	Number of patients with adverse event	None	191	2011	Pfizer	Industry
Comparison of Capso Vision SV-1 to PillCam SB2 in the Evaluation of Subjects With Suspected Small Bowel Disease	01787825	Age, Gender, Ethnicity, Race, Region of Enrollment	Comparison of diagnostic yield	None	121	2012	Caspo Vision, Inc.	Industry
Immune Response to the Human Papillomavirus Vaccine in Young Women With Inflammatory Bowel Disease	01034358	Age <18, Age between 16 and 85, age > 85, gender, disease activity at first HPV dose	12 month antibody response to HPV vaccine	None	15	2010	Merck + Mayo Clinic	Industry/Academic
A Multicenter, Postmarketing Study Evaluating the Concentration of Cimzia® in Mature Breast Milk of Lactating Mothers	02154425	Age <18, Age between 16 and 85, age >85, gender	Concentration of CZP in breast milk	None	17	2014	UCB Pharma	Industry

Source and notes: ClinicalTrials.gov (2018).

TABLE 2

Journal Articles Reporting ClinicalTrials.gov Trial Results

Paper	NCT	Demographic Attributes Reported	Results Reported	Table of Results?	Primary Outcome	Patient-Specific Data	Sample Size
Clowse, Megan EB, et al. "Minimal to no transfer of certolizumab pegol into breast milk: results from CRADLE, a prospective, postmarketing, multicentre, pharmacokinetic study." Annals of the rheumatic diseases (2017): annrheumdis-2017.	02154425	Age, Gender, Type of Arthritis, Weight, BMI, Infant Age ≤ 6 months, Infant Age >6 months-≤ 12 months, Infant age ≥ 12 months - ≤18 months, Infant Age, Infant Weight, Infant Length, Region	CZP in breastmilk by dosing regimen, Adverse effects by mother infant pair	Yes	Minimal/no transfer of CZP into breast milk, no PEG transfer	None	17
Colombel, Jean Frédéric, et al. "Infliximab, azathioprine, or combination therapy for Crohn's disease." New England Journal of Medicine 362.15 (2010): 1383-1395.	00094458	Gender, Race, Age, Weight, Disease duration, C-reactive protein, CDAI, Gastrointestinal area involved, corticosteroid, Budesonide, 5-Aminosalicylic compounds,	Patients with corticosteroid-free clinical remission by: Medication (Azathioprine, Infliximab, Combination), trial status, mean dose per day, Mucosal Healing, Adverse effects occurring in >10% of study group, Adverse effects of interest (Colon Carcinoma, Sepsis, Tuberculosis) Patients with Infusion Reaction	Yes	Patients with moderate-to-sever Crohn's disease who were treated with infliximab and azathioprine or infliximab alone were more likely to have a steroid-free clinical remission than those receiving azathioprine alone.	None	508
Colombel, Jean–Frédéric, et al. "Adalimumab induces deep remission in patients with Crohn's disease." Clinical Gastroenterology and Hepatology 12.3 (2014): 414-422.	00348283	Gender, Race, Age, CDAI, Disease Duration, CRP ≥1.0 mg/ld., CDAI score, SES-CD score, Prior anti-TNF agent, Concomitant medications, IBDQ, WPAI components	Monetary medical cost per subgroup (control, treatment), Hospitalization cost, other medical cost, indirect work loss cost, number of adverse effects by subgroup, number of completions, withdrawals of consent,	Yes	Patients given adalimumab had significant remission	None	129
Cranston, Ross D., et al. "A Pilot Study of the Prevalence of Anal Human Papillomavirus and Dysplasia in a Cohort of Patients With IBD." Diseases of the Colon & Rectum 60.12 (2017): 1307-1313.	01364896	Gender, Race, Age, Smoking, Years with IBD, Medication, Ulcerative colitis, Crohn's disease, Indeterminate colitis	Detection of anal HPVB by IBD cohort, gender, immunosuppressant use, and smoking status	No	Presence of HPV	None	46
Denson, Lee A., et al. "A randomized controlled trial of growth hormone in active pediatric Crohn's disease." Journal of pediatric gastroenterology and nutrition 51.2 (2010): 130.	00109473	Age, Gender, Tanner Stage, Disease Duration, Disease Location, Dosage, PCDAI, Fecal calprotectin, Pred. Dose, Bud. Dose, 6-MP dose, 6-MP duration, 5-ASA Dose	Demographic characteristics at 52 week extension Phase, Characteristics broken down by group (treatment, control): Mucosal Disease Activity, Clinical Disease Activity and Quality of Life, Corticosteroid Exposure, Nutritional Intake and Status, Circulating Growth Factors and Linear Growth,	Yes	Growth hormone did not create a reduction in inflammation relative to corticosteroids alone	None	20
Feagan, Brian G., et al. "Ustekinumab as induction and maintenance therapy for Crohn's disease." New England Journal of Medicine 375.20 (2016): 1946-1960.	01369329, 01369342, 01369355	Age, Gender, Duration of Disease, CDAI, median protein, GI areas involved, Medication for Crohn's Disease taken, history of TNF antagonist treatment, amount of drugs received, Nonresponse rate, unacceptable side effects	Adverse effects broken down by study (UNITI-1 UNITI-2 IM-UNITI), group (treatment, placebo)	No(plot)	Ustekinumab had a significantly higher effect in those with severe Crohn's Disease compared to the placebo	None	1766
Herfarth, Hans H., et al. "Ciprofloxacin for the prevention of postoperative recurrence in patients with Crohn's disease: a randomized, double-blind, placebo-controlled pilot study." Inflammatory bowel diseases 19.5 (2013): 1073-1079.	00609973	Gender, Age, duration of disease, smoker, number of resections, disease behavior, IBD drug therapy prior to surgery, Adverse events related to the study, adverse events unrelated to the study	Adverse effects broken down by group (Treatment, control), Number of patients in remission by group	Table of Adverse Effects, plots of results	Ciprofloxacin was not more effective than placebo for the prevention of recurrence of Crohn's disease.	None	33
Kamm, M. A., et al. "Adalimumab sustains steroid-free remission after 3 years of therapy for Crohn's disease." Alimentary pharmacology & therapeutics 34.3 (2011): 306-317.	00077779	Gender, Age, Weight, Involved Intestinal area, CDAI, C-Reactive protein, TNF-antagonist use, Medication, Current Smoker	Remission by dose, steroid use, and study (CHARM, ADHERE), at 24 week intervals, adverse effects by group (control, treatment)	Table of results, adverse effects	Adalimumab creates steroid free remission in a population with Crohn's disease	None	778

TABLE 2

Journal Articles Reporting ClinicalTrials.gov Trial Results

Paper	NCT	Demographic Attributes Reported	Results Reported	Table of Results?	Primary Outcome	Patient-Specific Data	Sample Size
Krier, Michael, et al. "Potential use of telemedicine to provide outpatient care for inflammatory bowel disease." The American journal of gastroenterology 106.12 (2011): 2063.	01296841	Age, gender, Race, Disease Duration, Ulcerative colitis, Crohn's disease, Duration, Wait time,	Duration, wait time, patient satisfaction by group (treatment, control)	Table, plot of results	IBD outpatient service can be delivered via a telemedicine system	None	34
Kumari, Meena, et al. "Vitamin D-mediated calcium absorption in patients with clinically stable Crohn's disease: A pilot study." Molecular nutrition & food research 54.8 (2010): 1085-1091.	00427804	Age, gender, race, BMI, duration of disease, creatnine clearance, serum, vitamin D intake, calcium intake	Results broken down by group(treatment, control, disease type): Serum and urine calcium, FCA, Adverse events. Note: 4/4 of the Crohn's Disease group were black	No table, results in text, plot of some results	Patients with Crohn's disease do not have impaired hormonal vitamin D absorption	None	9
Lee, Scott D., et al. "Reinduction with Certolizumab Pegol in Patients with Crohn's Disease Experiencing Disease Exacerbation: 7-Year Data from the PRECiSE 4 Study." Inflammatory bowel diseases 22.8 (2016): 1870-1880.	00160706	Age, Gender, Race, BMI, Duration of Disease, Creatinine clearance, Serum type, Vitamin D intake, Calcium intake	Reason for discontinuation by group (first exposure, first reinduction, remaintenance, overall) Adverse effect(leading to death, leading to withdrawal) by group, incidence rates for serious infections(by type of infection) and tumors(by type of tumor) by group	Table of results	CZM was effective in patients who previously stopped using it.	None	310
Leighton, Jonathan A., et al. "Capsule endoscopy is superior to small-bowel follow-through and equivalent to ileocolonoscopy in suspected Crohn's disease." Clinical Gastroenterology and Hepatology 12.4 (2014): 609-615.	00487396	Age, Height, weight, Gender, Change in Bowel Habit, Abdominal pain rectal bleeding, weight loss, inflammatory markers, anemia fevers, positive anti-Saccharomyces cerevisiae antibodies, Vomiting	Reasons for withdrawal/exclusion, number of lesions detected by capsule	No table, results in text	Capsule Endoscopy is equivalent to Ileocolonoscopy for detecting bowel inflammation.	None	80
Leighton, Jonathan A., et al. "Comparing diagnostic yield of a novel pan-enteric video capsule endoscope with ileocolonoscopy in patients with active Crohn's disease: a feasibility study." Gastrointestinal endoscopy 85.1 (2017): 196-205.	01631435	Gender, Age, Weight, Height, Clinical diagnosis: Chronic Abdominal pain, Chronic Diarrhea, Positive inflammatory markers, Anemia, Rectal bleeding, Weight Loss, Hypoalbuminemia	Cleansing level of bowel segment by group (SBC, ileocolonoscopy), Detection rate per segment by group, adverse effects by type of AE, adverse effects by relation to study intervention	Tables with results, results in text	Diagnostics for small bowel may be higher than ileocolonoscopy	None	114
Leonard, Mary B., et al. "Effect of Low-Magnitude Mechanical Stimuli on Bone Density and Structure in Pediatric Crohn's Disease: A Randomized Placebo-Controlled Trial." Journal of Bone and Mineral Research 31.6 (2016): 1177-1188.	00364130	Age, Gender, Race, Tanner Stage, Height, BMI, Time since Diagnosis, CDAI, Medications, Physical Activity, Calf Muscle Strength, Bone Strength	Overall(not broken down) change in height, BMI, PCDAI, dosage, medications, Broken down by group (treatment, placebo): DXA Tibia pQCT, Spine QCT, Tibia Metaphysis QCT, Bone Biomarkers, hospitalizations, reason for hospitalization, symptoms reported at study visit, growth and disease characteristics	Tables with results	Low magnitude mechanical stimuli has an inconsistent effect on bone structure	None	138
Lieske, John C., et al. "Diet, but not oral probiotics, effectively reduces urinary oxalate excretion and calcium oxalate supersaturation." Kidney international 78.11 (2010): 1178-1185.	00587041	Age, Gender, Kidney stones,	Broken down by group(control, treatment): urine indicators, quantitative stool cultures, Multivariate predictors of CaOx (regressors)	Extensive tables	Oxalate free diets reduced urinary oxalate concentration.	None	40

TABLE 2
Journal Articles Reporting ClinicalTrials.gov Trial Results

Paper	NCT	Demographic Attributes Reported	Results Reported	Table of Results?	Primary Outcome	Patient-Specific Data	Sample Size
Loftus, Edward V., et al. "Safety of Long-term Treatment With Certolizumab Pegol in Patients With Crohn's Disease, Based on a Pooled Analysis of Data From Clinical Trials." Clinical Gastroenterology and Hepatology 14.12 (2016): 1753-1762.	00291668, 00152425, 00308581, 00349752, 00552058, 00329550, 00329420, 00160524, 00160706, 00297648, 00333788, 00307931, 00356408, 00552344	Age, Age ≤30, Age >30-≤60, Age >60-≤64, Age >64, Gender, Race, BMI, CDAI, Duration of CD, Extent of CD, Behavior of CD, Resections performed, Number of Resections 1, 2,3, 3>	By group (control, treatment) Any skin events, serious skin events, malignancies of interest	Tables with results	Long term safety of CZP is similar to short term safety.	None	2570
Panaccione, Remo, et al. "Efficacy and safety of adalimumab in Canadian patients with moderate to severe Crohn's disease: results of the Adalimumab in Canadian SubjeCts with ModErate to Severe Crohn's DiseaSe (ACCESS) trial." Canadian Journal of Gastroenterology and Hepatology 25.8 (2011): 419-425.	00427921	Gender, Age, HBI, Length of Diagnosis, At least one draining of Fistula, Steroid Use, Immunosuppressant use, Amino salicylate Use, CRP, SIBDQ, Employed, WPAI component scores	Adverse effects broken down by: infliximab experienced, anti-TNF naïve, All Adalimumab, Efficacy broken down by group, work improvement (TWPI, WPAI), total activity impairment	Table with adverse effects, efficacy in text	Adalimumab created sustained steroid free remission	None	304
Panés, Julian, et al. "Tofacitinib for induction and maintenance therapy of Crohn's disease: results of two phase IIb randomised placebo-controlled trials." Gut 66.6 (2017): 1049-1059.	0139362, 01393899	Treatment Group, Gender, Age, Weight, Race, Duration of Disease, Prior Surgery, Extent of Disease, Use of TNFI, Use of corticosteroids , baseline CDAI, Baseline CRP, Baseline FCP	Adverse effects in the induction study and maintenance study broken down by group (Placebo, 5mg dosage, 10 mg dosage), Adverse effects recorded by frequency, severity, special effects of interest, serious infections, and laboratory parameters	Tables with adverse effects	Treatment group not significantly different from placebo group.	None	275
Regueiro, Miguel, et al. "Infliximab prevents Crohn's disease recurrence after ileal resection." Gastroenterology 136.2 (2009): 441-450.	00688636	Gender, Age ≥40, Smoker, Duration of Disease > 10, Disease location at surgery, Phenotype, Prior infliximab, Surgical resections 1, Surgical resections 2, Surgical resections 3, Concomitant immunomodulatory, Mesalamine agent, CDAI > 200, Age, Duration of Disease, ESR, CRP, CDAI	Measurements of efficacy by group (control and treatment), adverse effects by group, withdrawals from study due to adverse effects by group,	Tables with results and adverse effects, supplementary data available through link	The rate of recurrence in the treatment group was significantly lower than the rate of recurrence in the control group.	None	24
Sandborn, William J., et al. "Adalimumab for maintenance treatment of Crohn's disease: results of the CLASSIC II trial." Gut 56.9 (2007): 1232-1239.		Gender, Age, Body weight, Duration of Crohn's disease, smoker, enterocutaneous or perianal fistula, CDAI< IBDQ, CLASSIC, CRP, Concomitant drug treatment, Corticosteroid use, immunosuppressive agent, Crohn's-related antibiotics, 5-Amiosalicylates	IBDQ score every two weeks by group (control, treatment), adverse events by cohort (placebo, adalimumab 40mg weekly, adalimumab 40mg every other week)	IBDQ in plots, adverse events in table	Adalimumab induced and maintained remission for up to just over a year In patients with moderate to severe Crohn's disease	None	55
Sandborn, William J., et al. "Certolizumab pegol in patients with moderate to severe Crohn's disease and secondary failure to infliximab." Clinical Gastroenterology and Hepatology 8.8 (2010): 688-695.	00308581	Age, Age range, Gender, BMI, Duration of disease, Baseline CDAI, Geometric mean of baseline, Location of disease, Disease behavior, number of resections, history of infliximab, reason for infliximab failure,	Response rates (to medication) in each group (open-label induction, q2w maintenance, q4w maintenance) by covariates: CRP level, anti-infliximab antibody status, corticosteroid use, immunosuppressant use, CDAI score, history of resections, reason for infliximab failure, Crohn's Disease Duration, Adverse effects by group	Tables of response rates and adverse effects	Injection of adalimumab resulted in the remission of Crohn's disease among those resistant to steroid treatment.	None	539

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Sandborn, William J., et al. "Ustekinumab induction and maintenance therapy in refractory Crohn's disease." New England Journal of Medicine 367.16 (2012): 1519-1528.	00771667	Gender, Age, Weight, Duration of disease, CDAI, CRP, Crohn's disease drugs at baseline, Failure of previous treatment, TNF antagonist, Failure criteria met,	Effects of Ustekinumab by group (placebo, 1mg, 3mg ,6mg, combined) inducing remission and inducing a clinical response, any adverse event by group, common adverse events and serious adverse events by group	Clinical response and induced remission rates in graph, adverse effects rates in table	Ustekinumab treated patients who did not have a response to different medications are more likely to have a response but not likely to go into remission.	None	526
Sandborn, W. J., et al. "Randomised clinical trial: the safety and tolerability of Trichuris suis ova in patients with Crohn's disease." Alimentary pharmacology & therapeutics 38.3 (2013): 255-263.	01576461	Gender, Age, Race, Weight, Fecal calprotectin, C-reactive protein	Adverse effects by group (placebo, TSO 500, TSO 2500, TSO 7500), includes traffic accidents in AE,	Table of adverse effects	A single dose of Trichuris suis ova was tolerated and did not result in treatment related side effects.	None	12
Sandborn, William J., et al. "Vedolizumab as induction and maintenance therapy for Crohn's disease." New England Journal of Medicine 369.8 (2013): 711-721.	00783692	Age, Gender, Race, Weight, Smoker, Duration of Disease, CDAI score, C-reactive protein, fecal calprotectin, Disease site, Concomitant medications for Crohn's disease, Prior TNF antagonist therapy for Crohn's disease, Hemoglobin concentration, White-cell count, Prior surgery for Crohn's disease, History of fistulizing disease, Draining fistulae at baseline	Clinical remission rate, CDAI-100 response rate, glucocorticoid free remission rate, durable clinical remission rate by group (placebo, Vedolizumab 4wk, Vedolizumab 8 wk), adverse events, serious adverse events, serious infections, cancers by (placebo, Vedolizumab)	Rates in graphs, adverse effects in tables	Patients treated with Vedolizumab were more likely to have remission but not a CDAI-100 response	None	1115
Sandborn, W. J., et al. "Long-term safety and efficacy of certolizumab pegol in the treatment of Crohn's disease: 7-year results from the PRECiSE 3 study." Alimentary pharmacology & therapeutics 40.8 (2014): 903-916.	00552058	Age, Gender, Race, BMI, Disease duration, Location of Crohn's Disease, Behavior of Crohn's Disease, Prior infliximab use, Corticosteroid use, Immunosuppressant use, Use of both corticosteroid and immunosuppressant, Prior resections, Number of resections, Site of resections,	Adverse events by exposure group (first exposure, re-exposure, continuous exposure), relationship of adverse event to study drug (unrelated, unlikely, possible, probable, definite) Adverse events leading to death, adverse events leading to withdrawal, summary of infections and malignancies in the overall population	Tables of adverse events	Patients tolerated Certolizumab Pegol and some had sustained remission	None	117
Sandborn, William J., et al. "A phase 2 study of tofacitinib, an oral Janus kinase inhibitor, in patients with Crohn's disease." Clinical Gastroenterology and Hepatology 12.9 (2014): 1485-1493.	00615199	Gender, Age, Race, Weight, BMI, Smoking status, geographic region, duration since first diagnosis, disease location, CDAI score, CDAI category, CRP level, Fecal calprotectin level, Open draining enterocutaneous fistulas, immunosuppressant use within the previous 12 months, steroid use within the previous12 months, Anti-TNF use within the previous 12 months	Estimated response-70, estimated response-100, change in CRP, change in fecal calprotectin, change in by placebo and dosage, all-causality treatment-emergent adverse event (TEAE) treatment related TEAE, Serious adverse effects, patients discontinuing due to adverse effects, lipid assays at week 4 deaths, by group (placebo, 1mg, 5mg, 15mg),	Estimated response in graph with labeled numbers (strange line of fit)	Patients with Crohn's disease were not more likely to achieve response or remission than those receiving a placebo	None	139
Sandborn, William J., et al. "Phase II evaluation of anti-MAdCAM antibody PF-00547659 in the treatment of Crohn's disease: report of the OPERA study." Gut (2017): gutjnl-2016.	01276509	Age, Gender, Race, Weight, Smoking status, Disease duration, SES-CD total score, Site of colonoscopic abnormality, Fistulizing disease, hsCRP, Fecal calprotectin, Central memory CD4+ cells, CDAI score, Prior treatment strata, Current use of IS therapy, Current use of Steroids	Adverse effects by group (placebo, PF-00547659 22.5mg, 75mg, 225mg) CDAI-100 response by group at week 8 and 12, CDAI-remission by group at week 8 and 12, biomarker endpoints by group at week 8 and 12	Adverse effects, response, remission rates in tables, biomarker endpoints in graphs	CDAI-70 response was not significantly different.	None	265

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Sands, Bruce E., et al. "A randomized, double-blind, sham-controlled study of granulocyte/monocyte apheresis for active ulcerative colitis." Gastroenterology 135.2 (2008): 400-409.	00162942	Age, Gender, Race / ethnicity, Smoking status, Duration of Disease, Disease flares in past 12 months, Baseline CDAI, Concomitant drugs, Previous drugs for CD, prior surgery for CD	Summary of adverse effects by group (treatment, placebo), adverse effects occurring in >10% of patients by group, clinical remission and clinical response by group	Table of summary of adverse effects, clinical remission and clinical response discussed in text and shown in graph	Granulocyte/monocyte apheresis was well tolerated but not significantly more effective than a placebo.	None	235
Sands, Bruce E., et al. "Effects of vedolizumab induction therapy for patients with Crohn's disease in whom tumor necrosis factor antagonist treatment failed." Gastroenterology 147.3 (2014): 618-627.	01224171	Gender, age, weight, BMI, Disease duration, CDAI, CRP level, fecal calprotectin, disease localization, history of Crohn's disease surgery, History of fistulizing disease, corticosteroid use, immunosuppressive use, Mesalamine use, prior immunosuppressive use, prior TrTNF antagonist failure	Adverse effects, serious adverse effects, efficacy of Vedolizumab by group (control, treatment). Adverse effects which are apparent in >1% of patients were recorded	Table of adverse effects,	In patients with prior TNF antagonist failure, Vedolizumab was not significantly more effective than the placebo	None	416
Smith, Jill P., et al. "Therapy with the opioid antagonist naltrexone promotes mucosal healing in active Crohn's disease: a randomized placebo-controlled trial." Digestive diseases and sciences 56.7 (2011): 2088-2097.	00663117	Age, Gender, Prior anti-TNF treatment, Concomitant medications for Crohn's , Location of disease, CDAI, IBDQ, SF36, CRP, ESR,	Discontinuation due to adverse effects, clinical response by endoscopic assessment, clinical remission by endoscopic assessment, histology inflammation score, change in quality of life survey (IBDQ, SF36), CDAI scores, endoscopy score, adverse effects by number of patients (all by group treatment and control)	Tables of: adverse effects, everything else is in a graph and discussed in the text	Naltrexone Improves clinical activity of people with moderate to severe Crohn's disease compared to placebo.	None	40
Suskind, David L., et al. "Fecal microbial transplant effect on clinical outcomes and fecal microbiome in active Crohn's disease." Inflammatory bowel diseases 21.3 (2015): 556-563.	1757964	Gender, Age, Disease duration, Modified Paris Classification, disease location Concomitant IBD medications	PCDAI, CRP, Calprotectin, clinical remission, engraftment score, engraftment type, PRE-FMT similarity (each is broken down by a numbered patient and results were taken at 2 weeks, 6 weeks, 12 weeks) adverse events summary	Results are in a table, adverse events discussed in text	FMT for Crohn's disease may be a therapeutic option, further studies are needed.	Some	13
Wiese, Dawn M., et al. "Use of endoscopic ultrasound to guide adalimumab treatment in perianal Crohn's disease results in faster fistula healing." Inflammatory bowel diseases 21.7 (2015): 1594-1599.	00487396	Age, Gender, Race, Disease location, Disease Behavior, HBI, PDAI, rectovaginal Fistula, Seton placement, duration of seton	HBI, PCDAI, Fistula Drainage, Anti-TNF dosing recorded by group (control, treatment), adverse events (no adverse events reported)	Discussed in text and in chart	The use of Endoscopic Ultrasounds did not result in improved outcomes	None	20
Yang, Linlin, et al. "Therapeutic effect of vitamin d supplementation in a pilot study of Crohn's patients." Clinical and translational gastroenterology 4.4 (2013): e33.	00742781	Age, Gender, Body composition, multivitamin usage, Amino salicylates, purine analogs, TNF blockade, Opioid receptor antagonists, no medication, dietary characteristics.	Change in dietary characteristics, IBDQ, CDAI, adverse effects (number of events) all numbers not divided by group	All results in a table	Maintaining vitamin D levels in patients with mild Crohn's disease may be helpful	None	18

Source and notes: ClinicalTrials.gov (2018).