ONLINE RESOURCE 1 FOR:

The Future of Biosimilars: Maximising Benefits Across Immune-Mediated Inflammatory Diseases

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Supplementary Table 1 Available efficacy data on early treatment with TNF inhibitors in IBD

Study overview	**Location**	**Treatment groups (number of patients)**	**Results for primary efficacy endpoint, response measure or main outcome**
SONIC RCT (NCT00094458): A randomised, double-blind, 30-week trial, with 20-week blind extension in patients with CD naïve to azathioprine, 6-mercaptopurine, methotrexate or anti-TNF [1, 2]	92 centres (15 countries)	Infliximab (*n*=169) Azathioprine (*n*=170) Infliximab plus azathioprine (combination therapy; *n*=169)	Rate of corticosteroid-free clinical remission at week 26: 56.8% (combination therapy), 44.4% (infliximab) and 30% (azathioprine); *p*=0.006 for infliximab vs azathioprine; *p*<0.001 for combination therapy vs azathioprine; *p*=0.02 for combination therapy vs infliximab
Top-down vs step-up RCT (NCT00554710): A randomised, open-label, 2-year trial in patients with CD naïve to corticosteroids, antimetabolites or biologics with disease duration ≤4 years [3]	18 centres (Belgium, the Netherlands, Germany)	Induction with infliximab, plus maintenance with azathioprine (ECI; *n*=67) Induction with corticosteroids, with introduction of azathioprine and then infliximab as needed (conventional management; *n*=66)	Proportion of patients in remission at weeks 26 and 52: 60% (ECI) vs 35.9% (conventional management) at week 26 (*p*=0.0062); 61.5% (ECI) vs 42.2% (conventional management) at week 52 (*p*=0.0278)
TAILORIX RCT	27 centres	All patients received azathioprine, mercaptopurine or	Rate of corticosteroid-free remission at visits between week

(NCT01442025): A proof-of-concept, randomised, double-blind, controlled, 1-year trial in patients with luminal CD [4]	(Belgium, France, the Netherlands)	methotrexate plus infliximab. From week 14, infliximab dose increases (2 maximum) in 2.5 mg/kg increments to a maximum of 10 mg/kg based on clinical symptoms and biomarker analysis and/or serum infliximab concentrations (DIS 1; *n*=45), 5 mg/kg increments (maximally 1 time) to a maximum of 10 mg/kg based on the same criteria (DIS 2; *n*=37) or 5–10 mg/kg increments based on clinical symptoms only (controls; *n*=40)	22 and week 54, with absence of ulcers at week 54, no surgery for bowel resection and no new fistula: 33% (DIS 1), 27% (DIS 2) and 40% (control; *p*=0.5)
Early vs late treatment chart review: A retrospective medical record review with at least 3-year follow-up in patients with CD [5]	Single centre (South Korea)	Anti-TNF (with or without IM) initiated within 2 years of diagnosis (early TNF; *n*=79) IM (without anti-TNFs) initiated within 2 years of diagnosis (early IM; *n*=286) Anti-TNF (with or without IM) initiated more than 2 years after diagnosis (late therapy; *n*=305)	Proportion of patients undergoing intestinal surgery after treatment initiation: 16.9% (early TNF), 9.7% (early IM) and 26.9% (late therapy); the cumulative probability of intestinal surgery was significantly higher in the late vs early therapy groups ($p<0.001$)
Early vs late treatment claims review: A retrospective health claims review with up to 2-year follow-up in patients with CD [6]	Single claims database (>94 US health plans)	5-ASA and/or corticosteroids and/or IM prior to anti-TNF (*n*=1398) IM (excluding 5-ASA) prior to anti-TNF (IM-to-TNF; *n*=1031) Anti-TNF initiated within 30 days of first prescription for CD (early TNF; *n*=1321)	In general, lower relative risk of concomitant steroid use, CD-related surgery, anti-TNF dose escalation, anti-TNF discontinuation or switch over 24 months of follow-up in the early TNF group versus other two groups ($p<0.05$ for all comparisons except dose escalation in the IM-to-TNF vs early TNF groups)
Outcomes following infliximab cessation	Single centre (Korea)	Patients who ceased treatment following corticosteroid-free clinical remission for ≥1 year with	Cumulative relapse rates: After a median follow-up of 4.3 years, 60.3% of patients experienced a relapse.

chart review: A retrospective medical record review, with 1–8 years of follow-up of paediatric patients with CD [7]		infliximab and azathioprine (*n*=63)	Median time to relapse: 3.3 years after infliximab cessation Duration from diagnosis to infliximab treatment was positively associated with clinical relapse on univariate Cox analysis (HR 1.033 [95% CI 1.001–1.066]; *p*=0.046) but not on multivariate Cox analysis (*n*=48; HR 1.013 [95% CI 0.974–1.052]; *p*=0.519)
Escalation vs early treatment observational study: A prospective observational study with 54-week follow-up of paediatric patients with luminal CD [8]	Single centre (Korea)	Patients received oral corticosteroids, azathioprine and mesalazine. When response was refractory to or dependent on corticosteroids, infliximab was initiated (*n*=30) Azathioprine, mesalazine and infliximab initiated together without corticosteroids (ECI; *n*=48)	Mucosal healing at weeks 14 and 54 following infliximab initiation: early ECI was positively associated with mucosal healing at week 14 (*p*=0.02); ECI and mucosal healing at week 14 were positively associated with mucosal healing at week 54 on multivariate analysis (*p*=0.004 and *p*=0.02, respectively)
Step-up vs top-down chart review: A retrospective medical record review, with 3-year follow-up of paediatric patients with CD [9]	Single centre (Korea)	Induction with oral corticosteroids, mesalamine or azathioprine, plus infliximab for maintenance therapy (step-up; *n*=10) Induction and 1-year of maintenance with infliximab and azathioprine, followed by azathioprine only after 2 years (top-down; *n*=18)	Relapse rates during follow-up (according to PCDAI scores): 16.7% vs 50% at 1 year (*p*=0.091); 50% vs 90% at 2 years (*p*=0.048); 61.1% vs 90% at 3 years (*p*=0.194) in top-down and step-up groups, respectively. However, patients in the step-up group had a significantly longer disease duration
CALM RCT (NCT01235689): A randomised,	74 centres (22 countries)	Patients received prednisone induction and taper prior to randomisation, followed by escalation (no treatment, adalimumab induction, adalimumab	Proportion of patients with mucosal healing at week 48: 30.3% (clinical management) vs 45.9% (tight control; *p*=0.01)

open-label, active-controlled, 48-week, phase III trial of patients with CD with disease duration ≤6 years [10]		escalation, addition of azathioprine). Escalation was based on treatment failure, which was defined according to different criteria (tight control [*n*=122] vs clinical management [*n*=122])	
REACT cluster RCT (NCT01030809): An open-label, cluster, randomised controlled, 2-year trial of patients with CD [11]	41 centres (Belgium and Canada)	Patients with active disease after induction with corticosteroids received combination therapy with an anti-TNF and an antimetabolite (ECI; 22 centres; *n*=1084) Patients treated according to usual practice of their physicians (conventional management; 19 centres; *n*=898)	Mean proportion of patients in corticosteroid-free remission at month 12: 66% (ECI centres) vs 61.9% (conventional management centres; *p*=0.52)
CHARM RCT (NCT00077779) and ADHERE OLE (NCT00195715) subgroup analysis: A subgroup analysis of data from the CHARM randomised, double-blind, placebo-controlled 56-week trial, and the ADHERE OLE in	92 centres (Europe, US, Canada, Australia, South Africa) [13]	Patients received open-label induction with adalimumab followed by either adalimumab every other week, adalimumab weekly or placebo for the 52-week blinded phase of CHARM, following which, patients could enter the ADHERE OLE This study analysed data from patients in CHARM who were randomised into three categories based on disease duration at baseline (<2 years [*n*=93]; 2 to <5 years [*n*=148]; ≥5 years [*n*=536]) and were then followed through 3 years of treatment in the ADHERE OLE	Post-hoc analysis to assess the effect of disease duration on remission and response rates: at both weeks 26 and 56, patients with disease duration <2 years had numerically higher remission rates than those with longer disease durations; long-term remission rates were consistently higher from week 56 of CHARM through week 108 of ADHERE for the short-duration subgroup Clinical response followed the same pattern as clinical remission

patients with CD [12]			
PURSUIT-SC RCT (NCT00487539): A randomised, double-blind placebo-controlled trial in patients with moderate-to-severe UC with inadequate response or failure to tolerate ≥1 of 5-ASA, corticosteroids, azathioprine or 6-mercaptopurine, or corticosteroid-dependent patients (no minimum disease duration) [14]	217 sites (Europe, North America, Asia Pacific, South Africa, Israel)	Golimumab 400/200 mg (*n*=257) Golimumab 200/100 mg (*n*=253) Placebo (*n*=251) (phase III portion of the trial)	Clinical response rate at week 6: 54.9% (golimumab 400/200 mg), 51.0% (golimumab 200/100 mg) and 30.3% (placebo) ($p<0.0001$ for both golimumab groups vs placebo)
PURSUIT-IV RCT (NCT00488774): Patients with UC; eligibility criteria the same as for PURSUIT-SC [15, 16]	111 centres (Europe, North America, Asia Pacific)	Golimumab 1 mg/kg (*n*=61) Golimumab 2 mg/kg (*n*=75) Golimumab 4 mg/kg (*n*=77) Placebo (*n*=73) (phase III portion of the trial)	Clinical response at week 6 (exploratory analysis due to insufficient power): 36.1% (golimumab 1 mg/kg), 44.0% (golimumab 2 mg/kg), 41.6% (golimumab 4 mg/kg), 30.1% (placebo)
PURSUIT-M RCT	251 sites	Golimumab 100 mg (*n*=151)	Proportion of patients maintaining clinical response at week

(NCT00488631): Patients with UC completing PURSUIT-SC or PURSUIT-IV [17]	(Europe, North America, Asia Pacific, South Africa, Israel)	Golimumab 50 mg (*n*=151) Placebo (*n*=154)	54: 49.7% (golimumab 100 mg; $p<0.001$ vs placebo), 47.0% (golimumab 50 mg; $p=0.010$ vs placebo) and 31.2% (placebo)
Post-hoc analysis of PRECiSE 2 RCT (NCT00152425): Post-hoc analysis of factors influencing response in patients with active CD [18, 19]	147 sites (global)	Responders to 6 weeks of open-label certolizumab pegol induction therapy were randomised to certolizumab pegol 400 mg (*n*=215) or placebo (*n*=210). This analysis reported maintenance of response and remission in patients receiving maintenance certolizumab pegol therapy, by disease duration at baseline Disease duration <1 year (*n*=54) Disease duration ≥1–<2 years (*n*=42) Disease duration ≥2–<5 years (*n*=100) Disease duration ≥5 years (*n*=229)	Response rate at week 26: significantly greater with certolizumab vs placebo irrespective of disease duration (62.8% vs 36.2%; any disease duration; $p<0.001$); higher for those with disease duration <1 year vs ≥5 years (89.5% vs 57.3%; $p<0.05$) Remission rate at week 26: significantly greater with certolizumab pegol vs placebo for disease duration <1 year (68.4% vs 37.1%; $p<0.05$) and disease duration ≥5 years (44.3%vs 23.5%; $p<0.001$) Response and remission rates were numerically higher for patients with more recent diagnosis; no effects were statistically significant over the four groups
Analysis of PRECiSE 3 RCT (NCT00552058): Analysis of factors influencing long-term remission of patients with CD; eligible patients had	116 sites (North America, South America, Asia Pacific,	All patients received open-label certolizumab pegol in the PRECiSE 3 trial. This analysis reported univariate and multivariate regression analyses of time to loss of remission and maintenance of remission based on various clinical factors, including disease duration	Time to initial remission: Disease duration not a significant predictor Time to loss of remission: Disease duration not a significant predictor on univariate analysis (<24 months vs ≥24 months; $p=0.4020$) Maintenance of remission: Disease duration a significant

moderate-to-severe CD and had completed the PRECiSE 1 or 2 certolizumab pegol study [20, 21]	Europe, Israel)		predictor (OR 1.03; 95% CI 1.00–1.07; *p*=0.0488)
Post-hoc subgroup analysis of GEMINI 1 RCT (NCT00783718): Post-hoc analysis of efficacy outcomes in patients with UC who were TNF inhibitor-naïve or had experienced TNF inhibitor failure [22, 23]	211 centres (34 countries)	Patients were randomised to vedolizumab or placebo for the induction period, and responders re-randomised at week 6 for the maintenance period. Stratification factors included prior exposure to a TNF inhibitor and/or concomitant immunosuppressant use. This analysis considered patients by TNF inhibitor treatment history TNF inhibitor naïve (*n*=464) TNF inhibitor failure (*n*=367)	Clinical response rate at week 6: 53.1% (vedolizumab) vs 26.3% (placebo) in the TNF inhibitor-naïve population (RR 2.0; 95% CI 1.3–3.0) and 39.0% (vedolizumab) vs 20.6% (placebo) in the TNF inhibitor-failure population (RR 1.9; 95% CI 1.1–3.2) Clinical remission rate at week 52: 46.9% (vedolizumab) vs 19.0% (placebo) in the TNF inhibitor-naïve population (RR 2.5; 95% CI 1.5–4.0) and 36.1% (vedolizumab) vs 5.3% (placebo) in the TNF inhibitor-failure population (RR 6.6; 95% CI 1.7–26.5)
Post-hoc subgroup analysis of GEMINI 2 (NCT00783692) and GEMINI 3 (NCT01224171) RCTs: Post-hoc analysis of efficacy data from the placebo-controlled, 52-	GEMINI 2: 285 centres (39 countries) GEMINI 3: 107 centres (North America, Europe, Asia,	Patients were randomised to vedolizumab or placebo in the induction period of GEMINI 2 or GEMINI 3, stratified based on prior TNF inhibitor treatment. In GEMINI 2, at week 6, vedolizumab responders were re-randomised to vedolizumab or placebo, while non-responders continued vedolizumab and patients receiving placebo continued placebo This analysis pooled TNF inhibitor-naïve (*n*=516) and	Post-hoc analysis to assess the relationship between prior TNF inhibitor exposure and vedolizumab efficacy: Clinical remission rates at week 10 were significantly higher with vedolizumab than placebo in both TNF inhibitor-naïve (11.3% difference; 95% CI 1.5–21.1) and TNF inhibitor-failure (11.5% difference; 95% CI 4.5–18.6) subgroups; the difference was not statistically significant at week 6 for the TNF inhibitor-failure subgroup

week GEMINI 2 and 10-week GEMINI 3 studies in patients with CD [24-26]	Africa, Australia)	TNF inhibitor-failure (*n*=960) patients from both trials Descriptive summaries showed that TNF inhibitor-failure patients had a longer disease duration (range: 10.7–11.4 years) than TNF inhibitor-naïve patients (range: 5.3–7.0 years)	
Post-hoc analysis of GEMINI 1 (NCT00783718) RCT: Post-hoc analysis of early patient-reported outcomes from the GEMINI 1 trial (described above) in patients with UC [27]	As above	Patients were randomised to vedolizumab or placebo for the induction period, with stratification factors including prior use or non-use of TNF inhibitors This analysis compared the overall population (*n*=374), TNF inhibitor-naïve patients (*n*=206) and TNF inhibitor-exposed patients (*n*=168) Descriptive analysis showed that median disease duration was shorter in the TNF inhibitor-naïve population (placebo: 3.4 years; vedolizumab: 3.9 years) than the TNF inhibitor-exposed population (placebo: 5.3 years; vedolizumab 5.0 years)	Post-hoc analysis to explore the relationship between patient-reported outcomes in the induction period and prior TNF inhibitor exposure: Vedolizumab treatment significantly increased the proportion of patients reaching a composite rectal bleeding score of 0 and stool frequency score ≤1 vs placebo in the overall and TNF inhibitor-naïve, but not TNF inhibitor-exposed, subgroups, across time points
Post-hoc analysis of GEMINI 2 (NCT00783692) and GEMINI 3 (NCT01224171) RCTs: Post-hoc analysis of early	As above	Patients were randomised to vedolizumab or placebo for the induction period, stratified based on prior TNF inhibitor treatment This analysis compared the overall population (*n*=784), TNF inhibitor-naïve patients (*n*=286) and TNF inhibitor-exposed patients (*n*=498)	Post-hoc analysis to explore the relationship between patient-reported outcomes in the induction period and prior TNF inhibitor exposure: Vedolizumab treatment led to a significantly greater reduction in abdominal pain subscore vs placebo in the TNF inhibitor-naïve but not the TNF inhibitor-exposed population, and greater percentage reductions in the

patient-reported outcomes from the GEMINI 2 and 3 trials (described above) in patients with CD [27]		Descriptive analysis showed that median disease duration was shorter in the TNF inhibitor-naïve population (placebo: 3.6 years; vedolizumab: 4.5 years) than the TNF inhibitor-exposed population (placebo: 9.0 years; vedolizumab 9.3 years)	LSF subscore in both populations with vedolizumab vs placebo. Significantly greater percentages of patients achieved average abdominal pain scores ≤1 and LSF ≤3 with vedolizumab vs placebo in the TNF inhibitor-naïve but not TNF inhibitor-exposed group

5-ASA 5-aminosalicylate, *CD* Crohn's disease, *CI* confidence interval, *DIS* dose-intensification strategy, *ECI* early combined immunosuppression, *HR* hazard ratio, *IBD* inflammatory bowel disease, *IM* immunomodulatory, *LSF* loose stool frequency, *OLE* open-label extension, *OR* odds ratio, *PCDAI* Paediatric Crohn's Disease Activity Index, *RCT* randomised controlled trial, *RR* risk ratio, *TNF* tumour necrosis factor, *UC* ulcerative colitis, *US* United States

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Supplementary Table 2 References for Fig. 1 (biologics licensed by the FDA and/or EMA for the treatment of RA and/or IBD as of 25 November 2019). Biologics and biosimilars are categorised by biologic and presented in alphabetical order by brand name

Biologic or biosimilar	Regulatory document (year)	Reference
Abatacept		
Orencia	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125118s224lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/orencia-epar-product-information_en.pdf
Adalimumab		
Abrilada	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761118s000lbl.pdf
Amgevita	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/amgevita-epar-product-information_en.pdf
Amjevita	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761024s004lbl.pdf
Cyltezo	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761058s003lbl.pdf
Hadlima	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761059s000lbl.pdf
Halimatoz	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/halimatoz-epar-product-information_en.pdf
Hefiya	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/hefiya-epar-product-information_en.pdf
Hulio	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/hulio-epar-product-information_en.pdf
Humira	FDA approval letter (2018)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125057Orig1s411lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/humira-epar-product-information_en.pdf
Hyrimoz	FDA PI (2018)	https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761071Orig1s000ltr.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/hyrimoz-epar-product-information_en.pdf
Idacio	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/idacio-epar-product-information_en.pdf
Imraldi	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/imraldi-epar-product-information_en.pdf
Kromeya	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/kromeya-epar-product-information_en.pdf
Anakinra		
Kineret	FDA PI (2018)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103950s5182lbl.pdf

	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/kineret-epar-product-information_en.pdf
Certolizumab pegol		
Cimzia	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125160s293lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf
Etanercept		
Benepali	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/benepali-epar-product-information_en.pdf
Enbrel	FDA PI (2018)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103795s5569lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/enbrel-epar-product-information_en.pdf
Erelzi	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761042s010lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/erelzi-epar-product-information_en.pdf
Eticovo	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761066s000lbl.pdf
Lifmior	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/lifmior-epar-product-information_en.pdf
Golimumab		
Simponi	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125289s146lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/simponi-epar-product-information_en.pdf
Simponi Aria	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125433s028lbl.pdf
Infliximab		
Flixabi	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/flixabi-epar-product-information_en.pdf
Inflectra	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125544s009lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/inflectra-epar-product-information_en.pdf
Ixifi	FDA PI (2017)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761072s000lbl.pdf
Remicade	FDA PI (2018)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103772s5385lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/remicade-epar-product-information_en.pdf
Remsima	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/remsima-epar-product-information_en.pdf
Renflexis	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761054s009lbl.pdf

Zessly	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/zessly-epar-product-information_en.pdf
Natalizumab		
Tysabri	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125104s966lbl.pdf
Rituximab		
MabThera	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/mabthera-epar-product-information_en.pdf
Rituxan	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/103705s5457lbl.pdf
Rixathon	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/rixathon-epar-product-information_en.pdf
Riximyo	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/riximyo-epar-product-information_en.pdf
Truxima	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/truxima-epar-product-information_en.pdf
Sarilumab		
Kevzara	FDA PI (2018)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761037s001lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/kevzara-epar-product-information_en.pdf
Tocilizumab		
Actemra	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125276s127,125472s040lbl.pdf
RoActemra	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/roactemra-epar-product-information_en.pdf
Ustekinumab		
Stelara	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125261s142,761044s001lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/stelara-epar-product-information_en.pdf
Vedolizumab		
Entyvio	FDA PI (2019)	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125476s024lbl.pdf
	EMA SmPC (2019)	https://www.ema.europa.eu/en/documents/product-information/entyvio-epar-product-information_en.pdf

EMA European Medicines Agency, *FDA* United States Food and Drug Administration, *IBD* inflammatory bowel disease, *PI* Prescribing Information, *RA* rheumatoid arthritis, *SmPC* Summary of Product Characteristics