

# Head-to-head trials in IBD

	YEAR & NAME	IBD	DRUG/Intervention	RESULTS
Original biologic vs biosimilar	2017 NOR-SWITCH	IMIDS	IFX	CTP 13 = IFX originator
	2019 PLANET CD	CD	IFX	CTP 13 = IFX originator
	2021 VOLTAIRE-CD	CD	ADA	BI 695501 = ADA originator
Biologic vs Biologic	2019 VARSITY	UC	VDZ vs ADA	VDZ > ADA
	2020 VISIBLE 1	UC	VDZ IV vs SC	VDZ SC = VDZ IV
	2021 GARDENIA	UC	ETR vs IFX	ETR = IFX
	2021 IFX SC	IBD	IFX sc vs IFX IV	IFX IV = IFX SC
	2022 SEAVUE	CD	ADA vs UST	ADA = UST
	2022 HIBISCUS	UC	ETR vs ADA	ETR = ADA
	2023 VEGA	UC	GUS+GOL vs GUS vs GOL	GUS+GOL=GUS > GOL
	SEQUENCE*	CD	UST vs RIS	RIS > UST
	VIVID 1*	CD	UST vs MIRI	MIRI = UST
Other	2010 SONIC	CD	IFX-AZA vs IFX vs AZA	IFX-AZA > IFX > AZA
	2012 CYSIF	ASUC	IFX vs CICLO	IFX = CICLOSPORINE
	2012 SWITCH	CD	M-IFX vs S-ADA	MAINTAIN IFX > SWITCH TO ADA
	2014 UC-SUCCESS	UC	IFX-AZA vs IFX vs AZA	IFX-AZA > IFX = AZA
	2014 COMMIT	CD	IFX+MTX vs IFX	IFX+MTX = IFX
	2016 DIAMOND	CD	ADA+AZA vs ADA	ADA+AZA = ADA
	2016 CONSTRUCT	ASUC	IFX vs CICLO	IFX = CICLOSPORINE

Summarizing the complexity of these studies is impossible within such limited space; thus, this summary serves as a synthesis, but I recommend reading each study to grasp its design and full context.

\*Trials not published yet

Trials with 5ASA/thiopurines or those in postoperative CD will be summarized in a separate document

- GALAXI 1: not included because it was designed to compare GUS vs placebo, it included an arm on UST but used as a reference

Acronyms: ADA: adalimumab; ASUC: acute-severe ulcerative colitis; AZA: azathioprine; B2: structuring Crohn's; CD: crohn's disease, CYCLO: ciclosporine; EDB: endoscopic balloon dilatation; ETR: etrolizumab; IC: ileocaecal; FCSEMS: Fully covered self-expandable stents; GOL: golimumab; GUS: guselkumab; IMIDS: immune-mediated inflammatory disease; IFX: infliximab; IV: intravenous; MIRI: mirikizumab; MTX: methotrexate; SC: subcutaneous RIS: risankizumab; UC: ulcerative colitis, UST: ustekinumab; VDZ: vedolizumab



## Head-to-head trials in IBD II

	YEAR & NAME	IBD	DRUG/INTERVENTION	RESULTS
Other	2017 LIR!C	CD	IFX vs IC surgery	IFX = surgery
	2014 ADAFI	pCD	ADA+Cipro vs ADA	ADA+cipro > ADA
	2020 PISA-I	pCD	Seton vs aTNF vs aTNF+surgical closure	Stopped for futility
	2021 STRIDENT	B2-CD	ADA high+AZA vs ADA	ADA high+AZA = ADA
	2022 PISA-II	pCD	aTNF vs aTNF+closure	aTNF+surgical closure > aTNF
	2022 PROTDILAT	B2-CD	FCSEMS vs EDB	EDB > FCSEMS in CD stricture
Early therapy	2008 SUTD	CD	Ecombo vs standard	Ecombo induction > standard
	2015 REACT	CD	Combo vs standard	Early combo = standard
	2017 CALM	CD	Tight vs clinical management	Tight > clinical management
	2024 PROFILE	CD	Top-up vs accelerated step up	Top-down > accelerated step-up
IFX optimization	2015 TAXIT	CD	Clinical vs TC optimization	Clinical = TC optimization
	2018 TAILORIX	CD	Symptom vs Sympt+biomarker+ TC	Symptom = Sympt+biomarker + TC
	2021 PRECISION	IBD	IFX dose by Bayesian pk model vs no adjustment	IFX by Bayesian > no adjust
ADA optimization	2022 SERENE-CD	CD	ADA high induction vs ADA	ADA high induction = standard
	2022 SERENE-UC	UC	ADA high induction vs ADA	ADA high induction = standard
VDZ optimization	2022 ENTERPRISE	pCD	VDZ (0,2,6) vs (0,2,6,10)	VDZ (0,2,6) = (0,2,6,10)
	2024 ENTERPRET	UC	VDZ 300q8w vs intensif	VDZ 300 = VDZ intensified

Acronyms: ADA: adalimumab; ASUC: acute-severe ulcerative colitis; AZA: azathioprine; B2: structuring Crohn's; CD: Crohn's disease, CYCLO: ciclosporine; Combo: Early combination therapy; EDB: endoscopic balloon dilatation; ETR: etrolizumab; IC: ileocaecal; FCSEMS: Fully covered self-expandable stents; GOL: golimumab; GUS: guselkumab; IMIDS: immune-mediated inflammatory disease; IFX: infliximab; IV: intravenous; MIRI: mirikizumab; MTX: methotrexate; pCD: perianal Crohn's disease; SC: subcutaneous RIS: risankizumab; TC: trough concentrations; UC: ulcerative colitis, UST: ustekinumab; VDZ: vedolizumab

