Clinical experience with infliximab biosimilar

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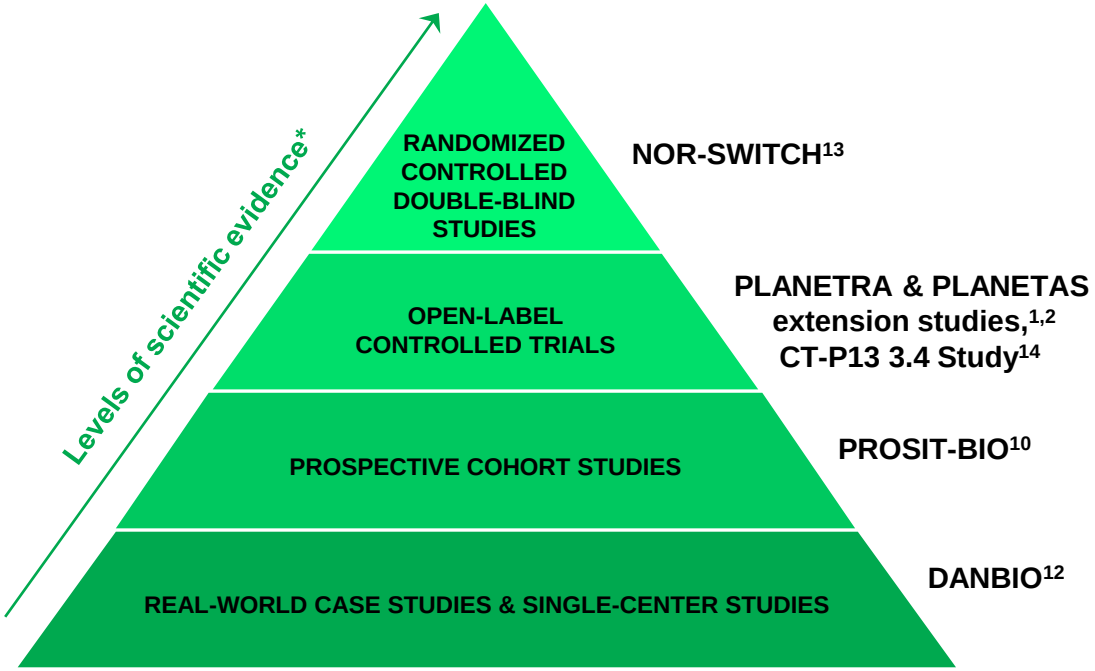
Conflict of Interest Statement

Consulting fees from Merck, Abbvie, Janssen, Genentech, Mitsubishi, Ferring, Norgine, Tillots, Vifor, Pharmacosmos, BMS, UCB-pharma, Hospira, Celltrion, Takeda, Biogaran, Boerhinger-Ingelheim, Lilly, Pfizer, HAC-Pharma, Index Pharmaceuticals, Amgen, Sandoz, Forward Pharma GmbH, Celgene, Biogen, Lycera, Samsung Bioepis.

Lecture fees from Merck, Abbvie, Takeda, Janssen, Ferring, Norgine, Tillots, Vifor, Mitsubishi, HAC-pharma.

Randomized Controlled Trials and Real-World Studies Support Switching From Originator Infliximab to CT-P13

Switching from originator infliximab to CT-P13 has demonstrated sustained clinical response and a comparable safety profile in randomized controlled studies, open-label extension studies, and real-world cohorts[1-14]

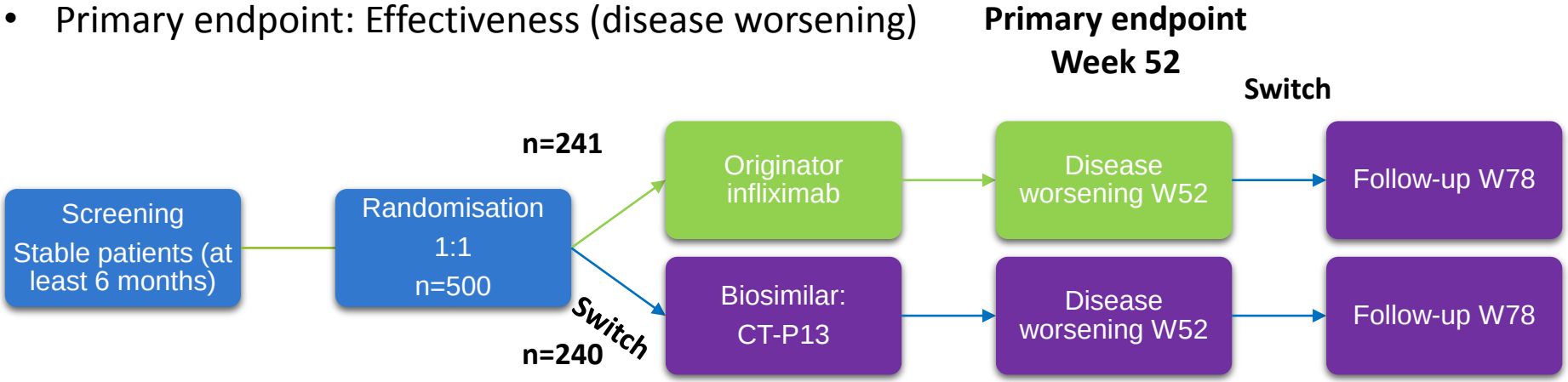


*Some real-world cases have not reported comparable results when switching from originator to biosimilars

1. Park W et al. *Ann Rheum Dis.* 2017;76(2):346-354. **2.** Yoo DH et al. *Ann Rheum Dis.* 2017;76(2):355-363. **3.** Kolar M et al. ECCO-IBD 2016. Abstract DOP032. **4.** Smits L et al. ECCO-IBD 2016. Abstract DOP030. **5.** Díaz Hernández L et al. ECCO-IBD 2016. Abstract P449. **6.** Batticciotto A et al. EULAR 2016. Abstract SAT0381. **7.** Park SH et al. *Expert Rev Gastroenterol Hepatol.* 2015;9(suppl 1):S35-S44. **8.** Jung YS et al. *J Gastroenterol Hepatol.* 2015;30(12):1705-1712. **9.** Hamanaka S et al. ECCO-IBD 2016. Abstract P329. **10.** Fiorino G et al. *Inflamm Bowel Dis.* 2017;23(2):233-243. **11.** Abdalla A et al. *Open Access Rheumatol*. 2017:9 29-35. **12.** Glintborg B et al. ACR 2016. Abstract 951. **13.** Jørgensen K et al. UEGW 2016. Abstract LB15. **14.** Kim YH et al. ECCO-IBD 2017. Abstract DOP061.

NOR- SWITCH Study design [1- 3]

- Exploring switching for non-medical reasons
- Primary endpoint: Effectiveness (disease worsening)



A randomized, double-blind, parallel-group study to evaluate the safety and efficacy of switching from innovator infliximab to biosimilar infliximab compared with continued treatment with innovator infliximab in patients with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease and chronic plaque psoriasis

Stable treatment with innovator originator infliximab during the last 6 months

Assumption : 30% worsening in 52 weeks
Non-inferiority margin:15%

Open Label Follow-up

W=week.

1. EudraCT Number: 2014-002056-40. https://www.clinicaltrialsregister.eu/ctr-search/trial/2014-002056-40/NO. Accessed May 15, 2017. 2. ClinicalTrials.gov. NCT02148640. Accessed May 15, 2017. 3. Jørgensen KK et al. *Lancet.* 2017. doi: http://dx.doi.org/10.1016/S0140-6736(17)30068-5. [Epub ahead of print].

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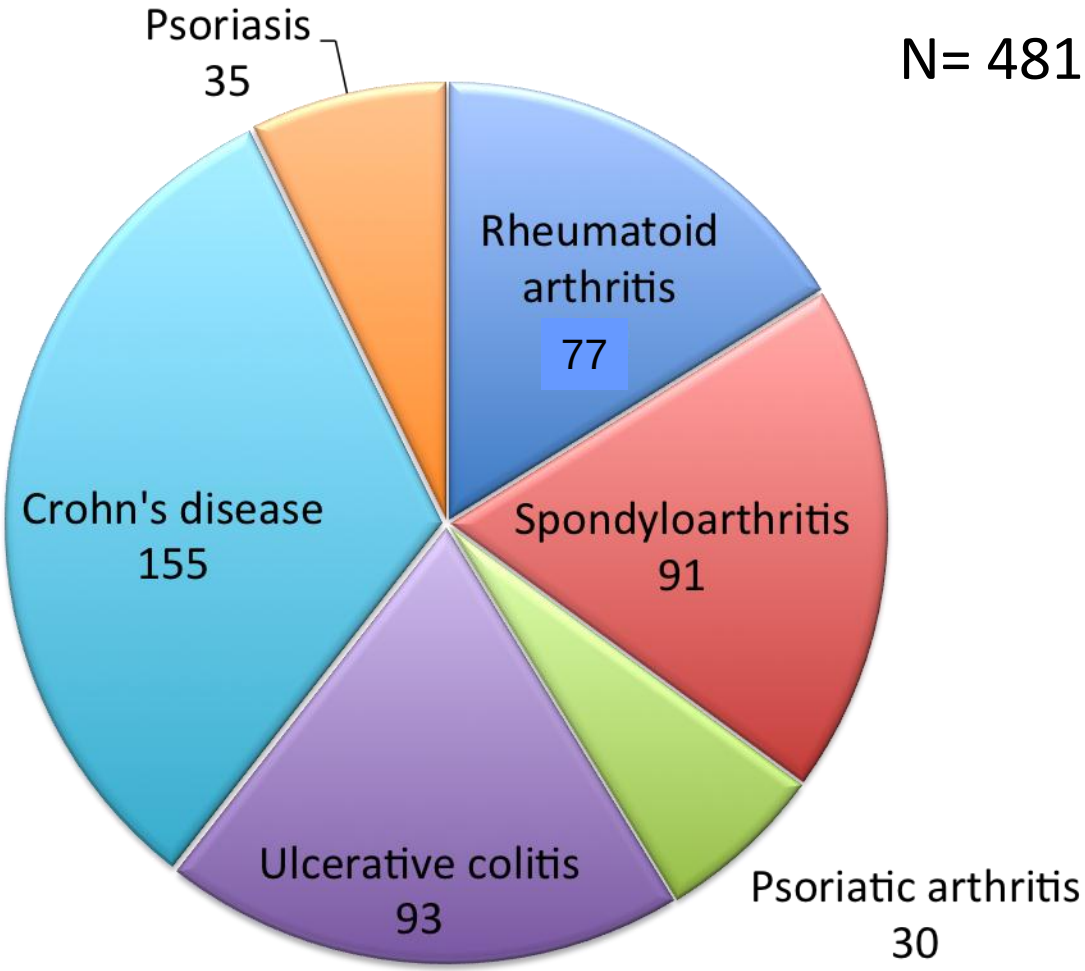
Diagnosis distribution



N= 481 (FAS)

FAS=full analysis set.

Jørgensen KK et al. *Lancet.* 2017. doi: http://dx.doi.org/10.1016/S0140-6736(17)30068-5. [Epub ahead of print].

Demographics and baseline characteristics

Overall	**INX (n=241)**	**CT-P13 (n=240)**
Age (years)	47·5 (14·8)	48·2 (14·9)
Female	99 (41·1%)	87 (36·2%)
Disease duration (years)	16·6 (10·9)	17·5 (10·5)
Duration of on-going INX treatment (years)	6·7 (3·6)	6·9 (3·8)
Previous therapy with biologics prior to INX		
TNFα inhibitors		
Not used	188 (78·0%)	188 (78·3%)
Used one	43 (17·8%)	40 (16·7%)
Used two	10 (4·1%)	9 (3·8%)
Used three or more	0 (0%)	3 (1·2%)
Other biologics	2 (0·8%)	1 (0·4%)
Concomitant immunosuppressive therapy *	113 (46·9%)	129 (53·8%)

*Methotrexate, leflunomide, sulphasalazine, azathioprine, and mercaptopurine.

Data are n (%), mean (SD), or median (25th–75th percentiles).
FAS=full analysis set; SD=standard deviation.
Jørgensen KK et al. *Lancet.* 2017. doi: http://dx.doi.org/10.1016/S0140-6736(17)30068-5. [Epub ahead of print].

Primary endpoint - PPS

	INX (n= 202)	CT-P13 (n=206)	Rate difference (95% CI)
Disease worsening*	53 (26.2%)	61 (29.6%)	-4.4 (-12.7 – 3.9)

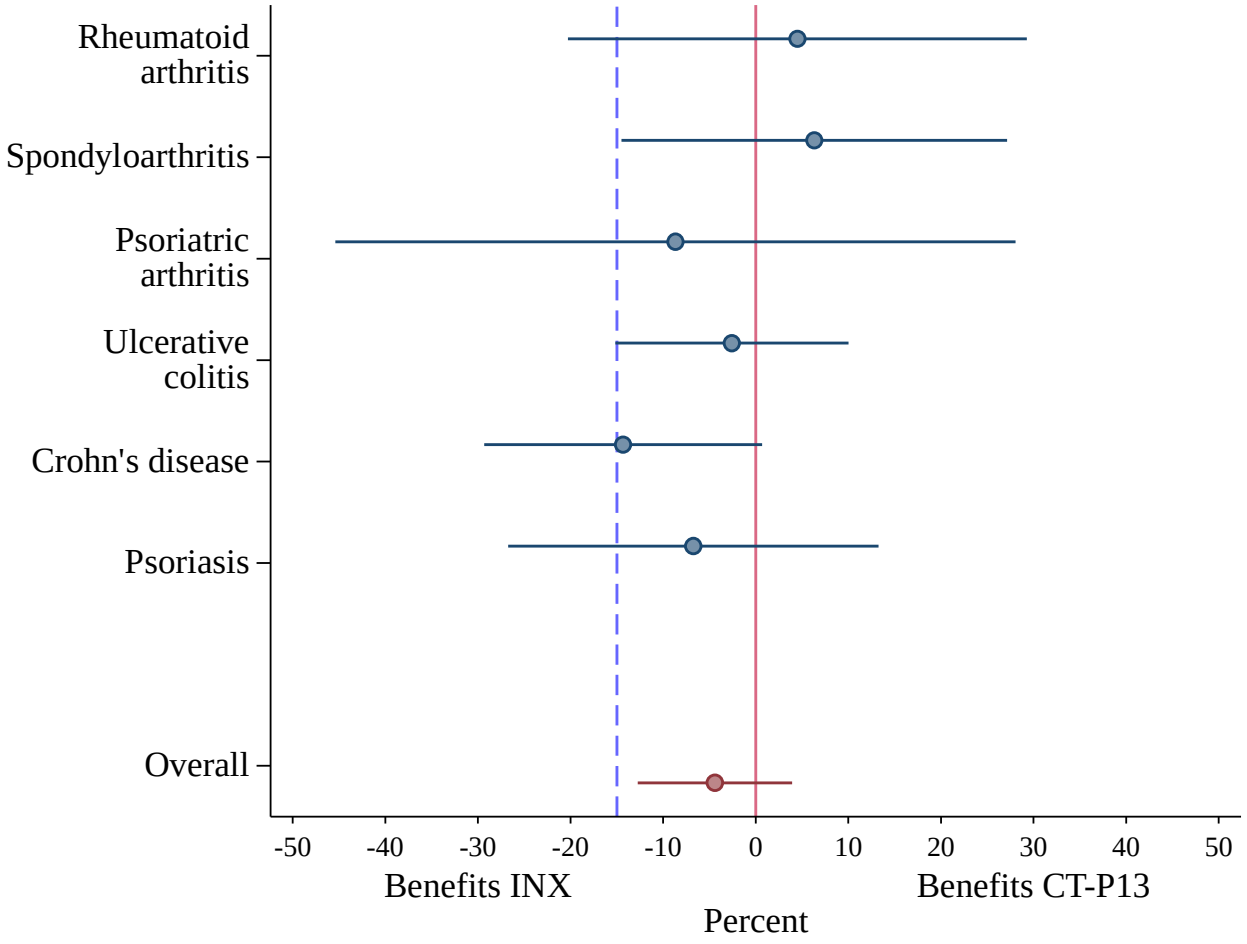
* UC: increase in p-Mayo score of ≥ 3 points and a p-Mayo score of ≥ 5 points,
CD: increase in HBI of ≥ 4 points and a HBI score of ≥7 points
RA/PsA: increase in DAS28 of ≥ 1.2 from randomization and a DAS score of ≥ 3.2
AS/SpA: increase in ASDAS of ≥1.1 and ASDAS of ≥ 2.1
Psoriasis: increase in PASI of ≥ 3 points from randomization and a minimum PASI score of ≥ 5

If a patient does not fulfill the formal definition, but experiences a clinically significant worsening according to both the investigator and patient and which leads to a major change in treatment this should be considered as a disease worsening but recorded separately in the CRF

ASDAS=Ankylosing Spondylitis Disease Activity Score; CD=Crohn's disease; CI=confidence interval; DAS28=Disease Activity Score in 28 joints; HBI=Harvey-Bradshaw index; PASI=Psoriasis Area and Severity Index; PPS=per-protocol set; PsA=psoriatic arthritis; PsO=psoriasis; RA=rheumatoid arthritis; SpA=spondyloarthritis; UC=ulcerative colitis.

Jørgensen KK et al. *Lancet.* 2017. doi: http://dx.doi.org/10.1016/S0140-6736(17)30068-5. [Epub ahead of print].

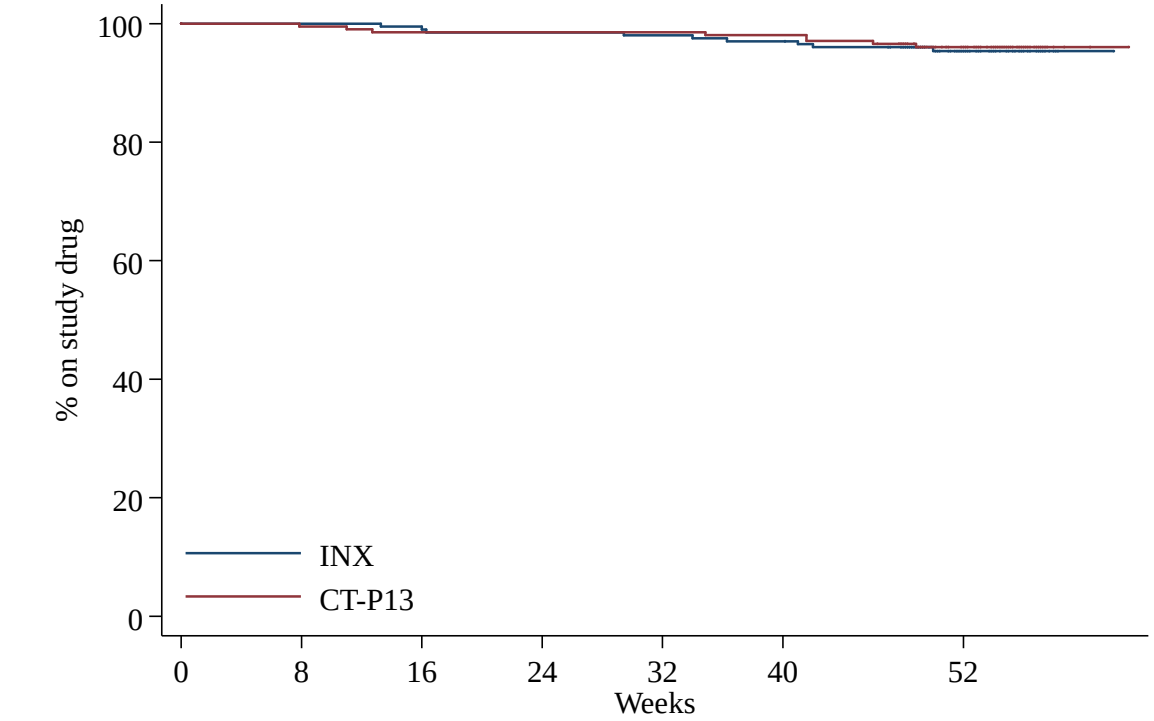
Disease worsening - PPS



CI=confidence interval; PPS=per-protocol set.

Jørgensen KK et al. *Lancet.* 2017. doi: http://dx.doi.org/10.1016/S0140-6736(17)30068-5. [Epub ahead of print].

Time to Study Drug Discontinuation - PPS

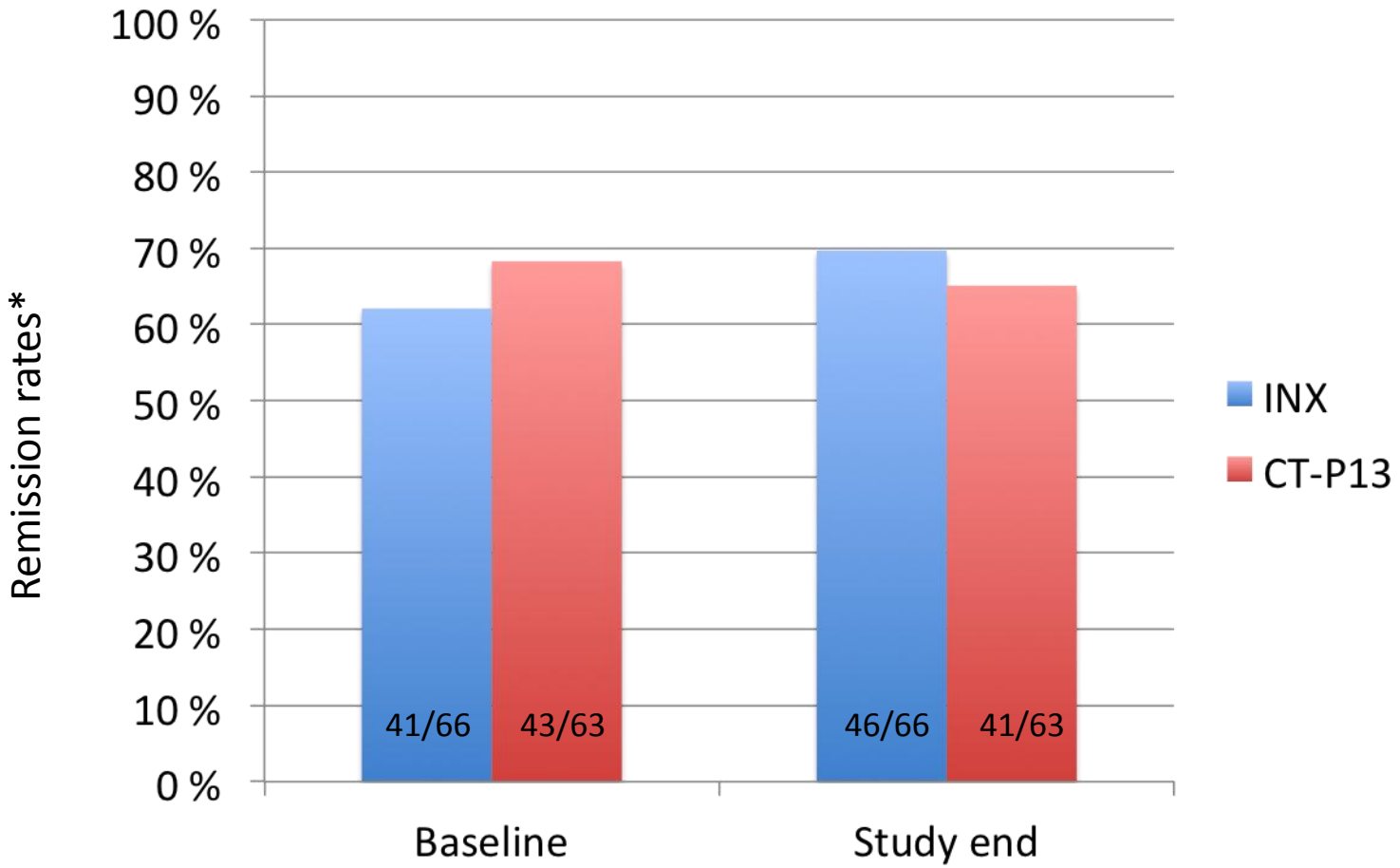


No. at risk							
INX	202	202	201	199	198	196	105
CT-P13	206	205	203	203	203	202	112

PPS=per-protocol set.

Jørgensen KK et al. *Lancet.* 2017. doi: http://dx.doi.org/10.1016/S0140-6736(17)30068-5 [Appendix]. [Epub ahead of print].

Crohns Disease



*Harvey Bradshaw Index ≤ 4

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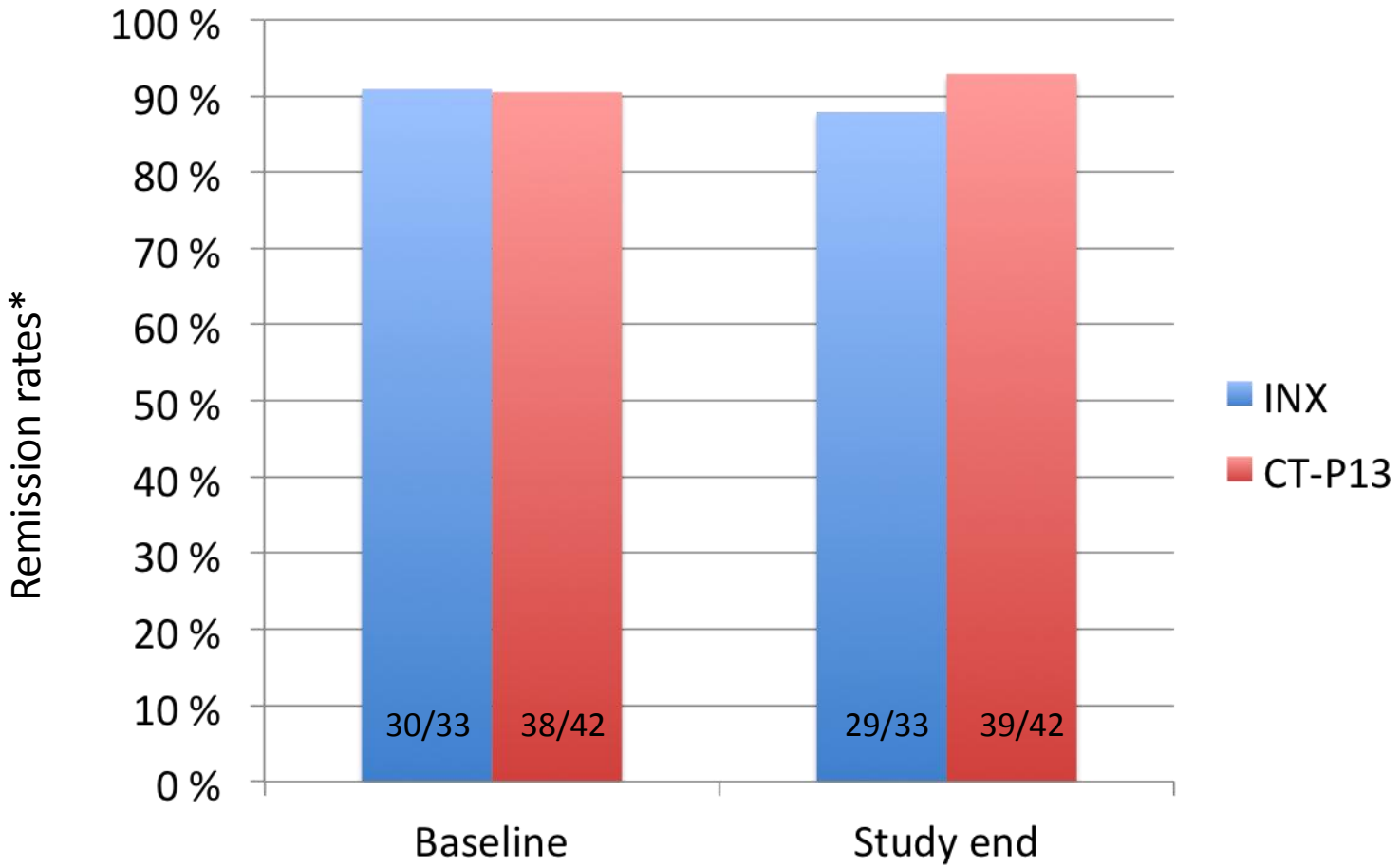
Ulcerative colitis



*p-Mayo score ≤ 2

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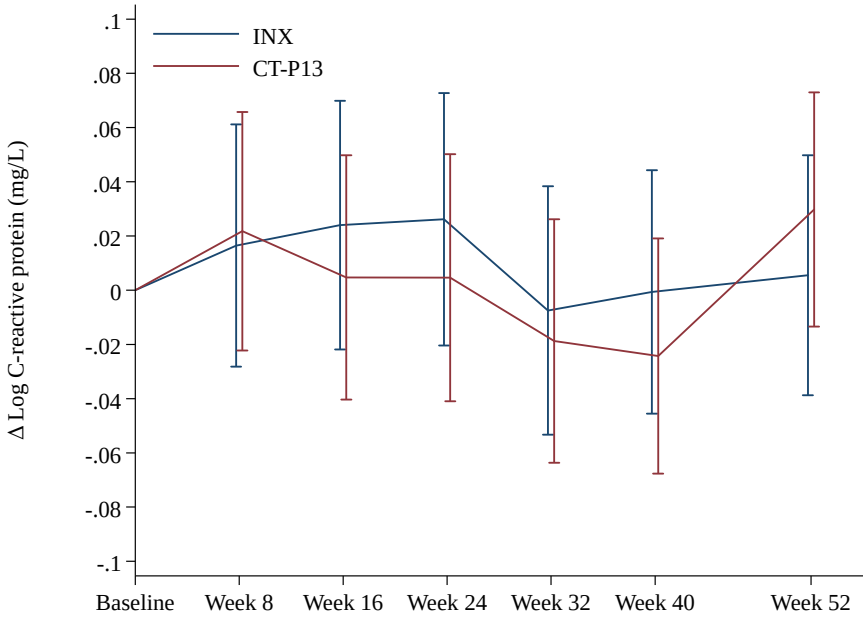
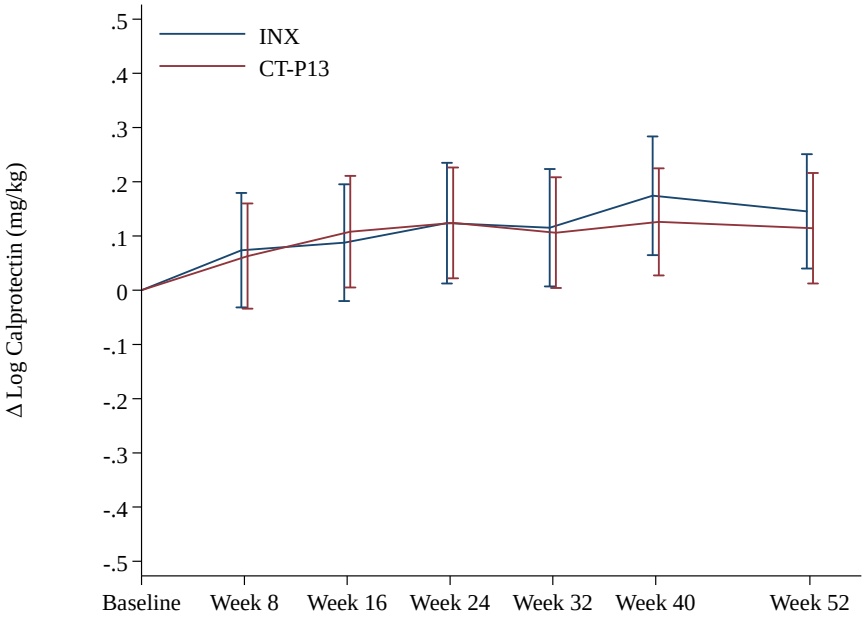
CRP and Calprotectin

Overall



CRP

IBD



Calprotectin

Jorgensen et al. UEGW 2016

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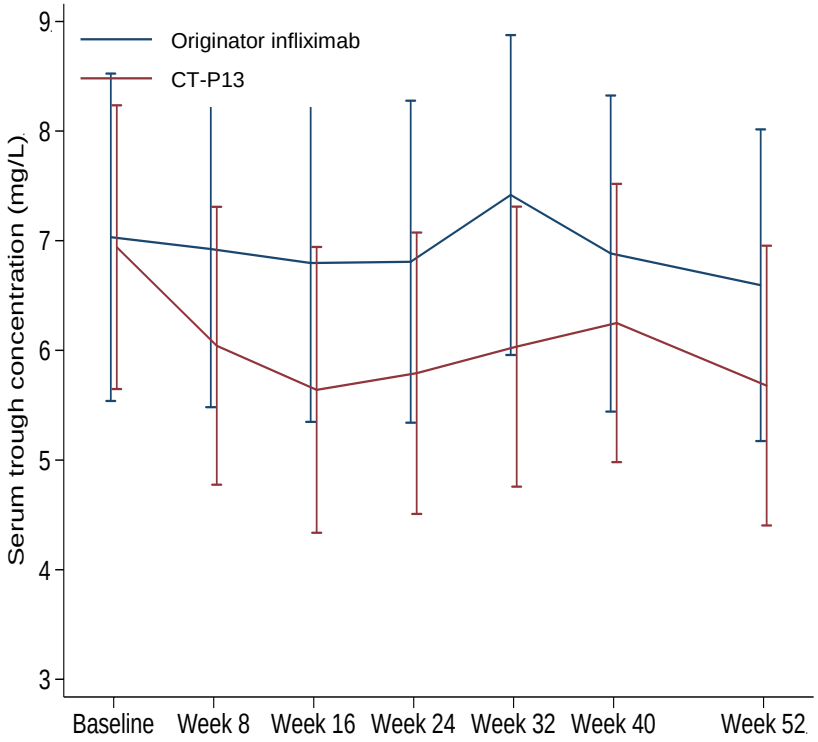
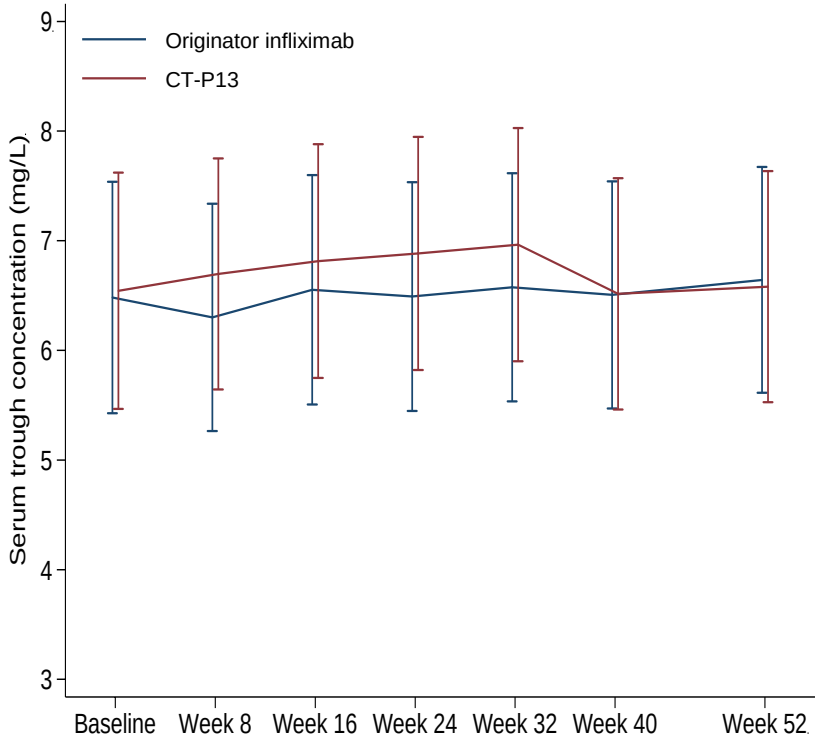
Drug trough levels



Ulcerative colitis

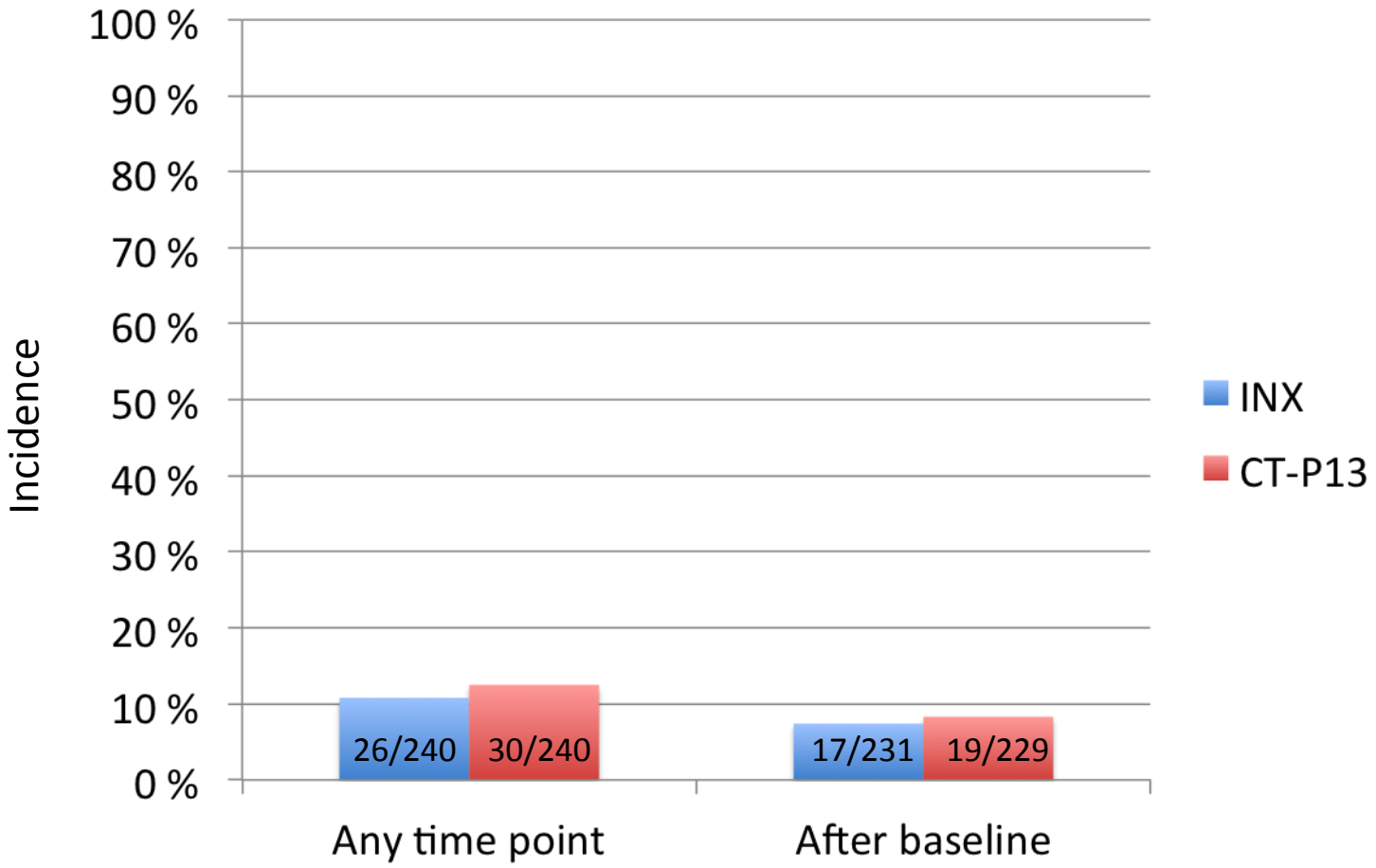


Crohns disease

NOR SWITCH

Jorgensen et al. UEGW 2016

Anti drug antibodies*



*neutralising antibodies, only measured in patients with drug trough level ≤ 5 mg/L

NOR SWITCH

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Adverse events

Overview *	INX (n=241)	CT-P13 (n=240)
SUSAR**	[0] 0 (0%)	[0] 0 (0%)
Serious adverse events (SAE)	[32] 24 (10·0%)	[27] 21 (8·8%)
Adverse events (AE)	[422] 168 (69·7%)	[401] 164 (68·3%)
Adverse event leading to study drug discontinuation	[18] 9 (3·7%)	[9] 8 (3·3%)

* [number of events] n (%)

** SUSAR= suspected unexpected serious adverse reaction

NOR SWITCH

Jørgensen KK et al. *Lancet.* 2017. doi: http://dx.doi.org/10.1016/S0140-6736(17)30068-5 [Epub ahead of print].

Interpretation

- The NOR-SWITCH trial demonstrated that switch from INX to CT-P13 was not inferior to continued treatment with INX.
- The results support switching from INX to CT-P13 for non-medical reasons.

NOR SWITCH

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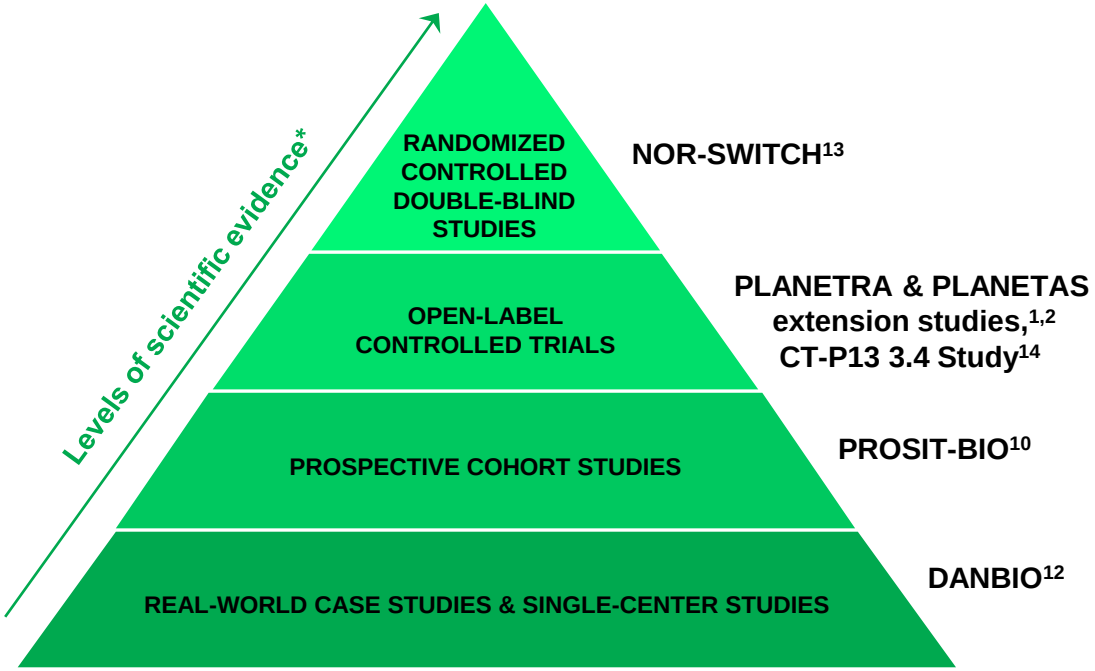

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CT-P13 3.4

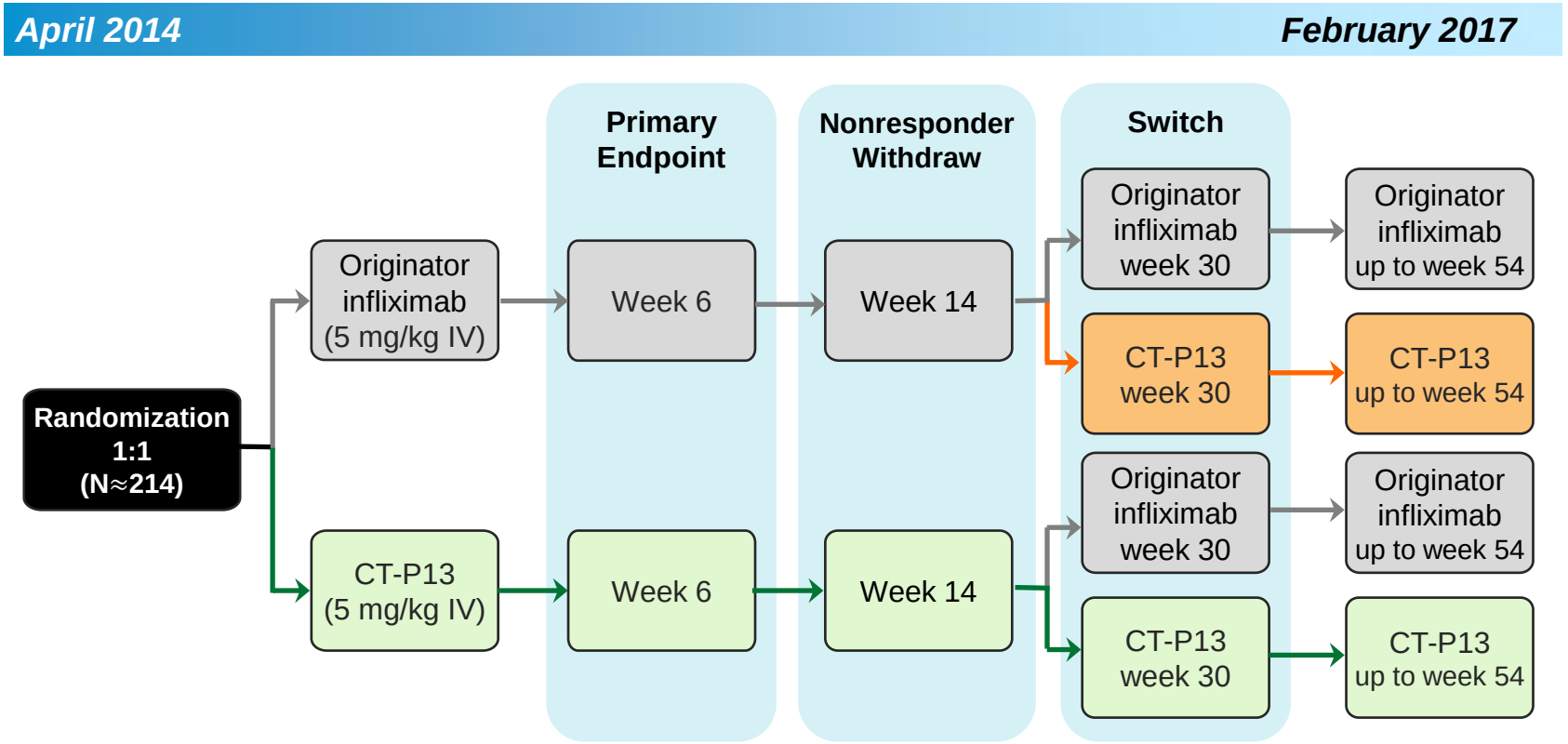
A Randomized, Double-Blind, Parallel-Group, Phase 3 Study to Demonstrate Noninferiority in Efficacy and to Assess Safety of CT-P13 Compared to Originator Infliximab in Patients With Active Crohn's Disease[1]

Trial identifiers: NCT02096861[1]
2013-004497-10[2]

1. ClinicalTrials.gov. Demonstrate noninferiority in efficacy and to assess safety of CT-P13 in patients with active Crohn's disease. https://clinicaltrials.gov/ct2/show/ NCT02096861. Accessed March 7, 2017. **2.** EU Clinical Trials Register. EudraCT Number: 2013-004497-10. https://www.clinicaltrialsregister.eu/ctr-search/trial/2013-004497-10/NL. Accessed March 7, 2017.

Study Design[1-3]

CT-P13 3.4



1. Data on file. Study CT-P13 3.4. Protocol version 2.2. February 10, 2015. Celltrion, Inc., Incheon, South Korea. **2.** ClinicalTrials.gov. Demonstrate noninferiority in efficacy and to assess safety of CT-P13 in patients with active Crohn's disease. https://clinicaltrials.gov/ct2/show/ NCT02096861. Accessed March 7, 2017. **3.** EU Clinical Trials Register. EudraCT Number: 2013-004497-10. https://www.clinicaltrialsregister.eu/ctr-search/trial/2013-004497-10/NL. Accessed March 7, 2017.

Exclusion criterion: Patient who has previously received a biological agent for the treatment of CD and/or a TNFα inhibitor for the treatment of other disease

Study Objectives

CT-P13 3.4

Primary:

- To demonstrate that CT-P13 is noninferior to originator infliximab at week 6 (dose 3) in terms of efficacy, as determined by the CDAI 70 response rate

Secondary:

- To evaluate long-term secondary efficacy of CT-P13 in comparison with originator infliximab up to week 54
- To evaluate overall safety of CT-P13 in comparison with originator infliximab up to week 54

EU Clinical Trials Register. EudraCT Number: 2013-004497-10. https://www.clinicaltrialsregister.eu/ctr-search/trial/2013-004497-10/NL. Accessed March 7, 2017.

Results: Efficacy—Per-Protocol Population

CT-P13 3.4

	CT-P13 (n=105)	Originator infliximab (n=101)
CDAI 70 response n (%), CI*	75 (71.4%) [61.8, 79.8]	76 (75.2%) [65.7, 83.3]
CDAI 100 response n (%), CI*	65 (61.9%) [51.9, 71.2]	65 (64.4%) [54.2, 73.6]
Clinical remission n (%), CI*	45 (42.9%) [33.2, 52.9]	45 (44.6%) [34.7, 54.8]
*95% confidence interval.		

Kim YH et al. Abstract DOP 061. Presented at European Crohn's and Colitis Organisation—Inflammatory Bowel Diseases. Barcelona, Spain. February 15-18, 2017.

Results: Efficacy

CT-P13 3.4

- 220 patients were randomized at baseline
- 214 patients completed the study up to week 6

- **At week 6, the CDAI 70 response rate of CT-P13 was similar to that of originator infliximab :**
  - 71.4% for CT-P13 vs 75.2% for originator infliximab (*P*=0.5613)

- **Similar and consistent trends were observed in patients achieving:**
  - **CDAI 100**
    - 61.9% for CT-P13 vs 64.4% for originator infliximab (*P*=0.7744)
  - **Clinical remission**
    - 42.9% for CT-P13 vs 44.6% for originator infliximab (*P*=0.8329)

Kim YH et al. Abstract DOP 061. Presented at European Crohn's and Colitis Organisation—Inflammatory Bowel Diseases. Barcelona, Spain. February 15-18, 2017.

Results: Safety

CT-P13 3.4

- The number of patients with at least 1 treatment-emergent adverse event (TEAE) was similar between groups:
  - CT-P13 = 30.6% (34/111)
  - Originator infliximab = 35.8% [39/109]
- The number of patients with at least 1 treatment-emergent serious adverse event (TESAE) was also similar between groups:
  - CT-P13 = 1.8% (2/111)
  - Originator infliximab = 1.8% (2/109)
- There was no notable difference in TEAEs of special interest between groups:
  - Infusion-related reactions:
    - CT-P13 = 5.4% (6/111)
    - Originator infliximab = 5.5% (6/109)
  - Infections:
    - CT-P13 = 2.7% (3/111)
    - Originator infliximab = 1.8% (2/109)

Kim YH et al. Abstract DOP 061. Presented at European Crohn's and Colitis Organisation—Inflammatory Bowel Diseases. Barcelona, Spain. February 15-18, 2017.

.

Conclusion

CT-P13 3.4

- The efficacy of CT-P13 was similar to originator infliximab in terms of CDAI 70, CDAI 100, and clinical remission up to week 6 in patients with CD
- CT-P13 was well-tolerated with a similar safety profile to that of originator infliximab up to week 6
- These results are consistent with observations from other studies[1-3]

1. Colombel JF et al. *N Engl J Med*. 2010;62(15):1383-1395. **2.** Gecse KB et al. 2016;4(5S):A59-60. **3.** Jørgensen KK et al. *United European Gastroenterol J*. 2016;2(suppl 1).

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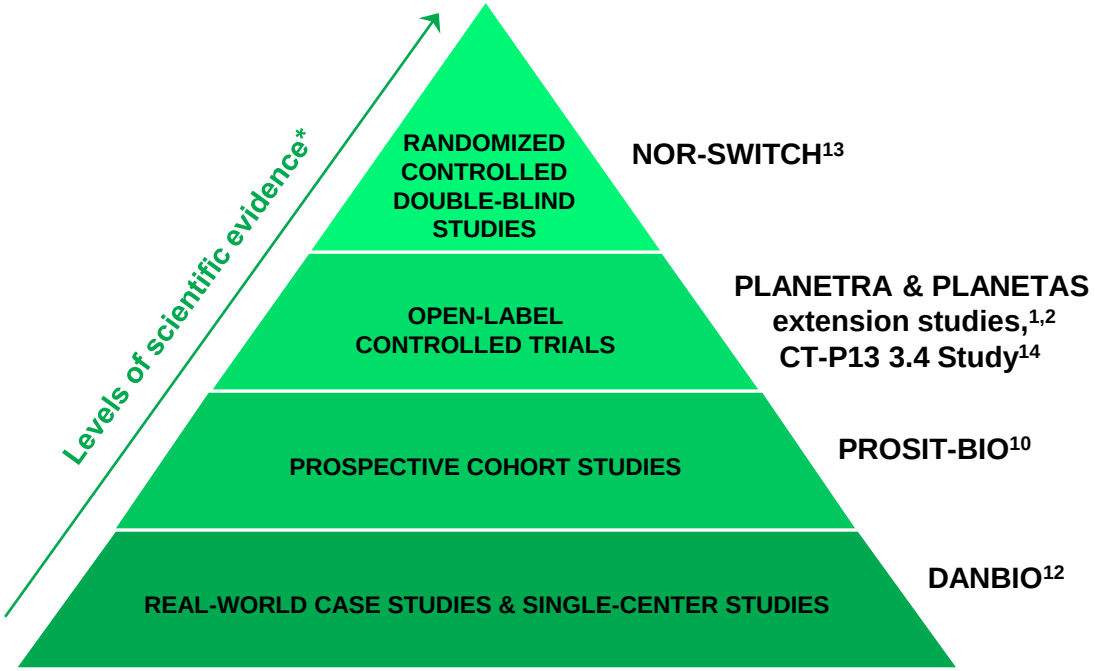

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The PROSIT cohort of infliximab biosimilar in IBD: a prolonged follow-up on the efficacy and safety across Italy

Guidi, L.[1], Fiorino, G.[2], Variola, A.[3], Manetti, N.[4], Fries, W.[5], Rizzuto, G.[6], Bossa, F.[7], Cappello, M.[8], Biancone, L.[9], D'Incà, R.[10], Cantoro, L.[11], Castiglione, F.[12], Principi, M.[13], Annunziata, M.L.[14], Di Girolamo, M.[15], Terpin, M.M.[16], Cortelezzi, C.C.[17], Costa, F.[18], Amato, A.[19], Di Sabatino, A.[20], Saibeni, S.[21], Meucci, G.[22], Petruzzellis, C.[23], Tari, R.[24], Gugliemi, F.W.[25], Armuzzi, A.[26], Danese, S.[2], Geccherle, A.[3], Rogai, F.[4], Ventra, A.[5], Orlando, A.[6], Andriulli, A.[7], Scrivo, B.[8], Troncone, E.[9], Caccaro, R.[10], Kohn, A.[11], Nardone, O.[12], Annese, V.[27]

[1]Complesso Integrato Columbus, Fondazione Policlinico Gemelli Università Cattolica, Internal Medicine and Gastroenterology, Rome, Italy, [2]Humanitas Research Hospital and University, Gastroenterology and IBD Center, Rozzano, Italy, [3]Sacro Cuore Don Calabria Hospital, Gastroenterology and Hepatology, Negrar, Italy, [4]AOU Careggi, DEA, Gastroenterology, Florence, Italy, [5]University of Messina, Clinical Unit for Chronic Bowel Disorders, Messina, Italy, [6]Riuniti Villa Sofia - Cervello Hospital, Internal Medicine 2, Palermo, Italy, [7]IRCCS-CSS Hospital, Gastroenterology, San Giovanni Rotondo, Italy, [8]University Hospital, Gastroenterology, Palermo, Italy, [9]Tor Vergata, Gastroenterology, Roma, Italy, [10]University of Padova, Gastroenterology, Padova, Italy, [11]S. Camillo-Forlanini Hospital, Gastroenterology, Rome, Italy, [12]Federico II University, Gastroenterology, Naples, Italy, [13]University Bari, Gastroenterology, Bari, Italy, [14]IRCCS Policlinico, Gastroenterology & Digestive Endoscopy Unit, San Donato, Milano, Italy, [15]University Hospital, Gastroenterology, Modena, Italy, [16]AO Hospital, Gastroenterology and Endoscopy, Legnano, Italy, [17]AOU di Circolo Fondazione Macchi, Gastroenterology, Varese, Italy, [18]AOUP, Gastroenterology, Pisa, Italy, [19]Ospedale Valduce, Gastroenterology, Como, Italy, [20]S.Matteo Hospital Foundation, University of Pavia, First Department of Medicine, Pavia, Italy, [21]ASST Rhodense, Gastroenterology Unit, Rho, Italy, [22]S. Giuseppe Hospital, Gastroenterology, Milano, Italy, [23]Poliambulanza Hospital, Gastroenterology and Digestive Endoscopy, Brescia, Italy, [24]AOU Maggiore, Gastroenterology, Novara, Italy, [25]S. Pellegrino Hospital, Gastroenterology, Trani, Italy, [26]Complesso Integrato Columbus - Catholic University, Internal Medicine and Gastroenterology, Rome, Italy, [27]Valiant Clinic, Gastroenterology, Dubai, United Arab Emirates

Guidi L et al. ECCO-IBD 2017. Abstract OP005.

Study design

Multicenter real-life study across referral centers in Italy

All consecutive patients undergoing therapy with CT-P13 were prospectively included since March 2015

Study population

1. Naïve to infliximab (never exposed)
2. Previously exposed to anti-TNF
3. Switched from originator

Guidi L et al. ECCO-IBD 2017. Abstract OP005.

Study definitions

Safety

Number of patients with adverse events
(any AE; infusion reactions; and AEs leading to discontinuation)

Efficacy

UC

Response: >30% AND 3 points reduction in MCS
Remission: MCS <2 with no partial scores >1

CD

Response: 3-point in HBI OR 100-point reduction in CDAI
Remission: HBI ≤ 4 or CDAI <150

Immunogenicity

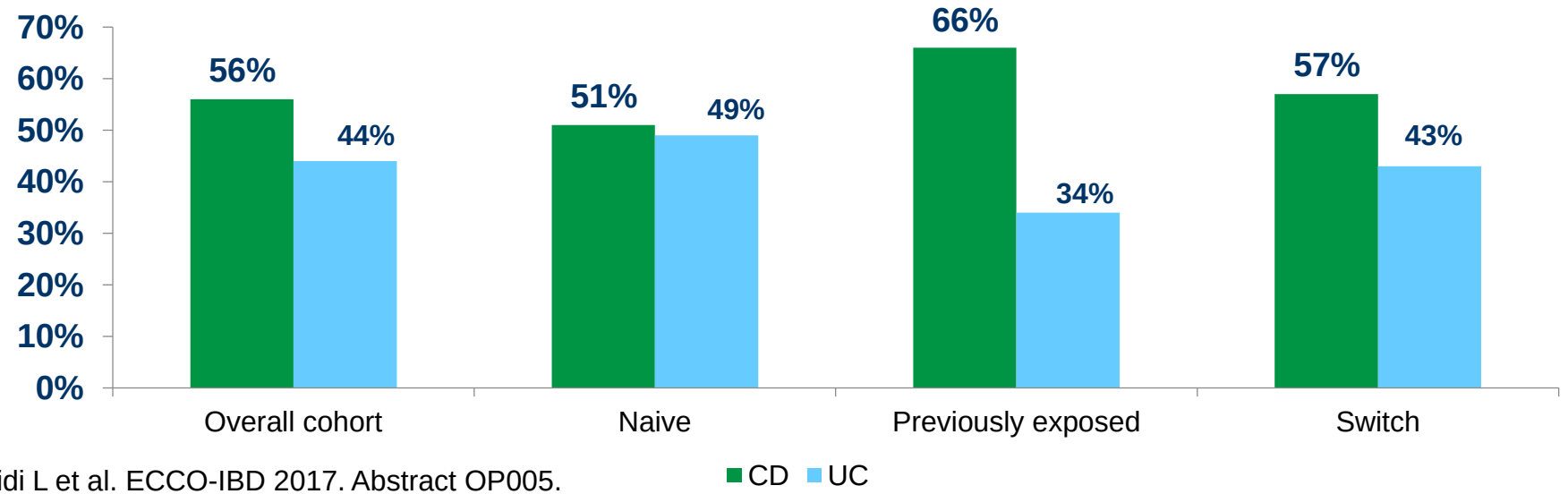
Dosage of TL and ADA (to be determined by further analyses, still ongoing)

Guidi L et al. ECCO-IBD 2017. Abstract OP005.

Results

Study population

- **801 patients** enrolled in 33 referral Centers:
  - **462 patients** were **naïve to anti-TNFα**
  - **193 patients** had a **previous exposure to one o more biologics (43** exposed to IFX originator**)**
  - **146 patients** switched from IFX originator to CT-P13

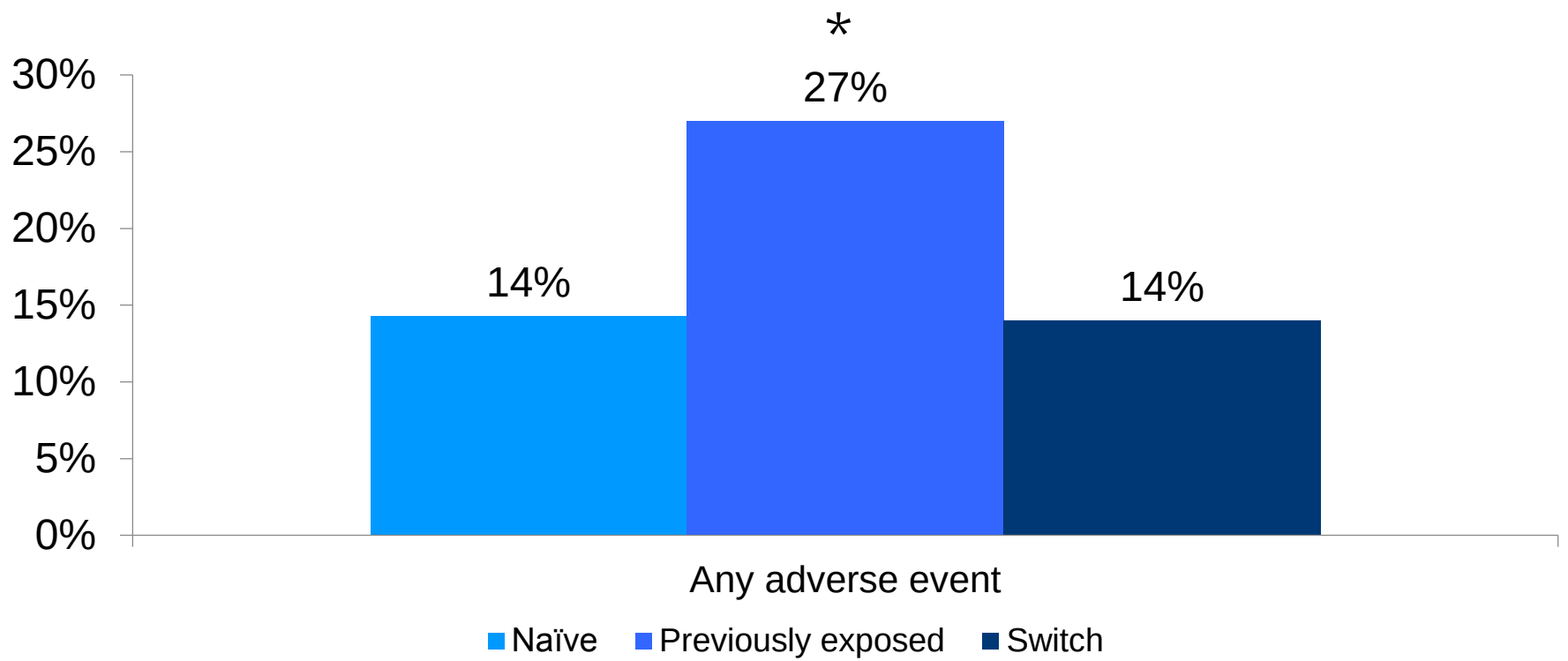


Guidi L et al. ECCO-IBD 2017. Abstract OP005.

Safety (any adverse event)

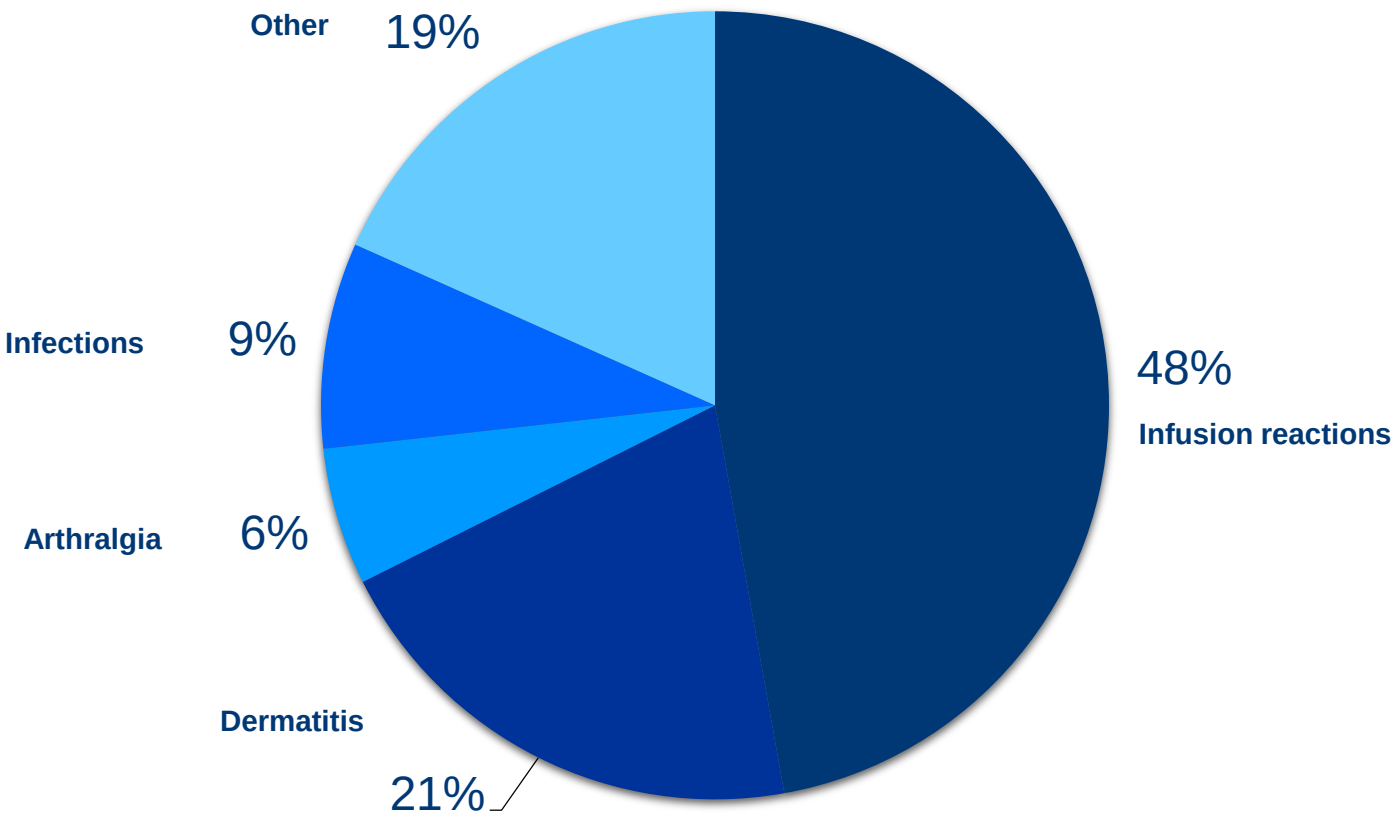
Incidence Rate Ratios

Naïve vs. Switched	**1.26** (0.76–2.20), p = NS
Naïve vs. Previously exposed	**0.51** (0.35–0.75), p < 0.001
Previously exposed vs. Switched	**2.48** (1.46–4.37), p < 0.001



Guidi L et al. ECCO-IBD 2017. Abstract OP005.

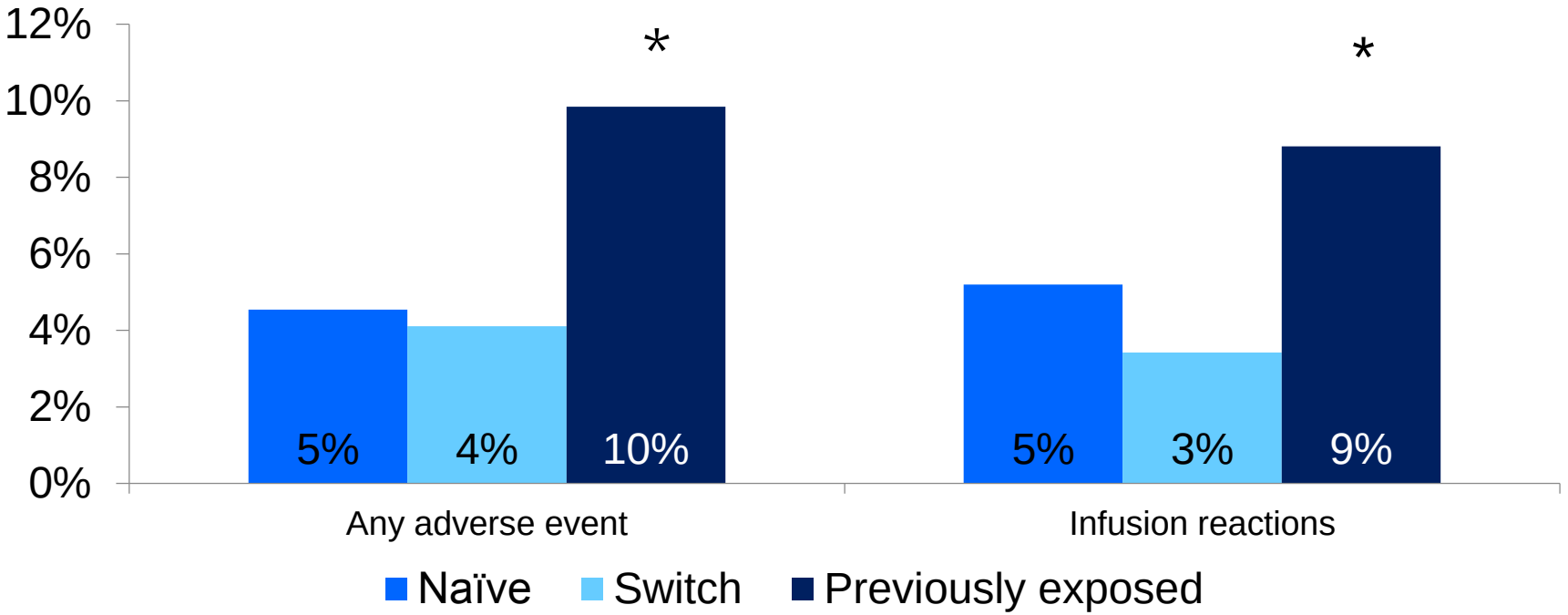
Adverse events (n=139)



Guidi L et al. ECCO-IBD 2017. Abstract OP005.

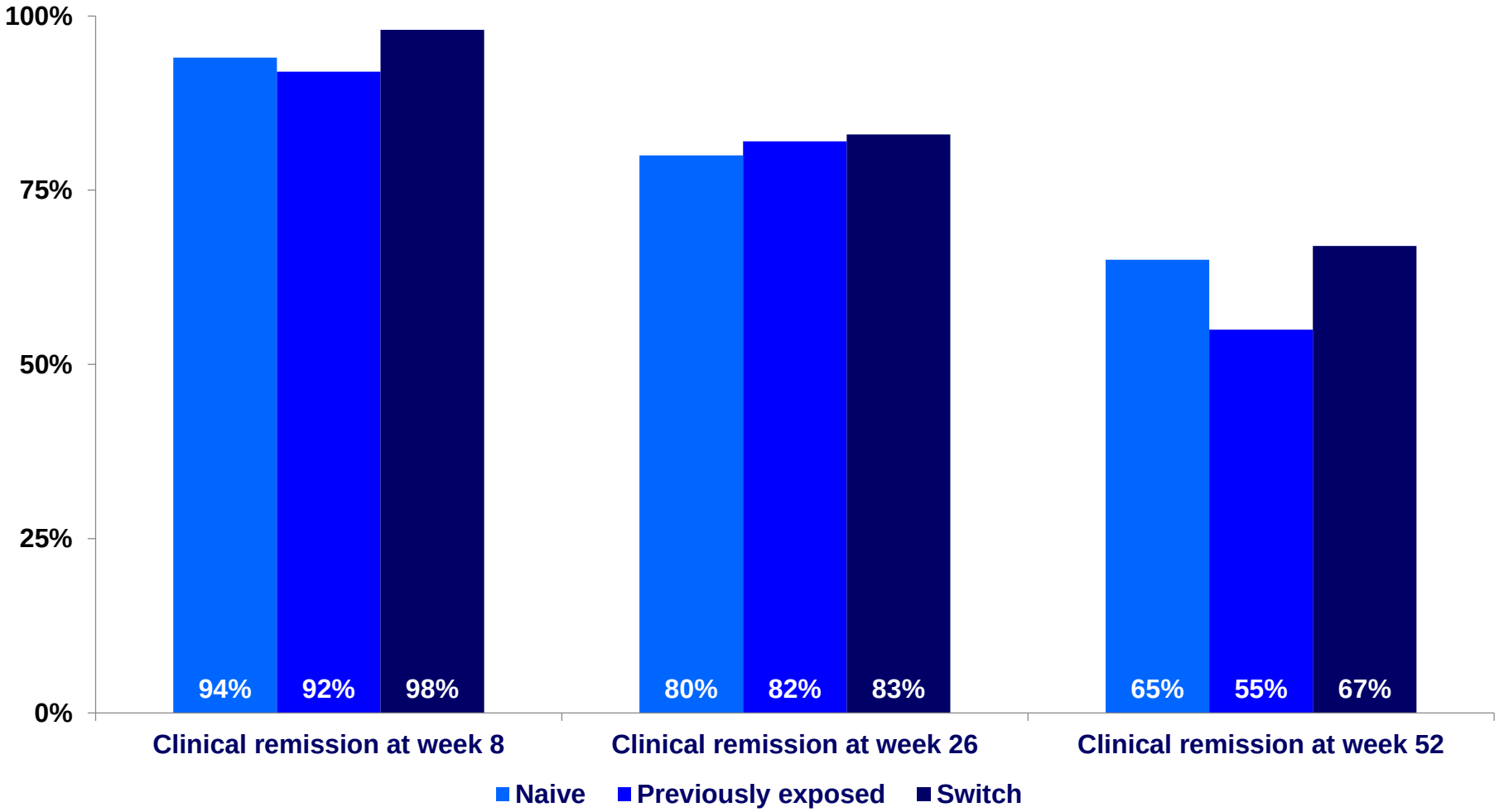
Adverse events leading to discontinuation

	Other AEs	P value	Infusion reactions	P value
Naive vs. previously exposed	IRR: **0.45** (0.23–1.89)	*0.015*	IRR: **0.58** (0.30–1.15)	*NS*
Naive vs. switch	IRR: **1.34** (0.52–4.06)	*NS*	IRR: **1.83** (0.69–6.17)	*NS*
Previously exposed vs. switch	IRR: **2.98** (1.14–9.05)	*0.015*	IRR: **3.17** (1.12–11.0)	*0.016*



Guidi L et al. ECCO-IBD 2017. Abstract OP005.

Treatment persistency (n=633*)



*Patients with treatment duration > 8 weeks

Guidi L et al. ECCO-IBD 2017. Abstract OP005.

Clinical activity and Biomarkers

Crohn's disease (n=222)

Marker	Baseline	Week 52	p value
HBI	7.1 ± 3.4	3.2 ± 2	<0.01
SES-CD	10.1 ± 42	3 ± 2.6	<0.01
CRP (mg/L)	1.9 ± 1.7	0.9 ± 0.8	<0.01
Fecal calprotectin (mg/kg)	565 ± 485	126 ± 133	<0.01

Ulcerative colitis (n=89)

Marker	Baseline	Week 52	p value
Partial Mayo Score	6.1 ± 2.3	1.9 ± 1.8	<0.01
Mayo endoscopic subscore	2.1 ± 0.6	1.3 ± 0.8	<0.01
CRP (mg/L)	3 ± 2	0.9 ± 0.7	<0.01
Fecal calprotectin (mg/kg)	759 ± 516	72 ± 65	<0.01

Guidi L et al. ECCO-IBD 2017. Abstract OP005.

Summary on Switching From Originator Infliximab to CT-P13: Take-Home messages

- Clinical data from randomized comparative studies consistently support that switching from originator infliximab to CT-P13 maintains comparable efficacy and safety[1-3]
- Clinical experience shows comparable nature and rates of AEs and SAEs between CT-P13 and originator infliximab[3-5]
- The immunogenicity profiles of CT-P13 and originator infliximab have been shown to be comparable in clinical studies[1-5]
- Switching from an originator to a biosimilar in patients with IBD is considered acceptable and should be performed following appropriate discussion between health care providers and patients[6]

AE, adverse event; IBD, inflammatory bowel disease; SAE, serious adverse event.

1. Yoo DH et al. *Ann Rheum Dis.* 2017;76(2):355-363. **2.** Park W et al. *Ann Rheum Dis.* 2017;76(2):346-354. **3.** Jørgensen K et al. UEGW 2016. Abstract LB15. 4. Yoo DH et al. *Arthritis Res Ther.* 2016;18(1):82. **5.** Park W et al. *Arthritis Res Ther.* 2016;18(1):25. **6.** Danese S et al. *J Crohns Colitis*. 2017;11(1):26-34.

Topline Summary:

ECCO Position Statement on the Use of Biosimilars for Inflammatory Bowel Disease – An Update

The statement conveys 8 key points about biosimilars :

1. Biosimilarity is more sensitively characterized by performing suitable *in vitro* assays than clinical studies
2. Clinical studies of equivalence in the most sensitive indication can provide the basis for extrapolation. Therefore data for the usage of biosimilars in IBD can be extrapolated from another sensitive indication
3. When a biosimilar product is registered in the EU, it is considered to be as efficacious as the reference product when used in accordance with the information provided in the SmPC
4. Demonstration of safety of biosimilars requires large observational studies with long-term follow-up in IBD patients. This should be supplemented by registries supported by all involved stakeholders (manufacturer, healthcare professionals, and patients' associations)
5. Adverse events and loss of response due to immunogenicity to a biologic drug cannot be expected to be overcome with a biosimilar of the same molecule
6. As for all biologics, traceability should be based on a robust pharmacovigilance system and the manufacturing risk management plan
7. Switching from the originator to a biosimilar in patients with IBD is acceptable. Studies of switching can provide valuable evidence for safety and efficacy. Scientific and clinical evidence is lacking regarding reverse switching, multiple switching, and cross-switching among biosimilars in IBD patients
8. Switching from originator to a biosimilar should be performed following appropriate discussion between physicians, nurses, pharmacists, and patients, and according to national recommendation. The IBD nurse can play a key role in communicating the importance and equivalence of biosimilar therapy

IBD, inflammatory bowel disease; SmPC, Summary of Product Characteristics.

Danese S et al. *J Crohns Colitis*. 2017;11(1):26-34.