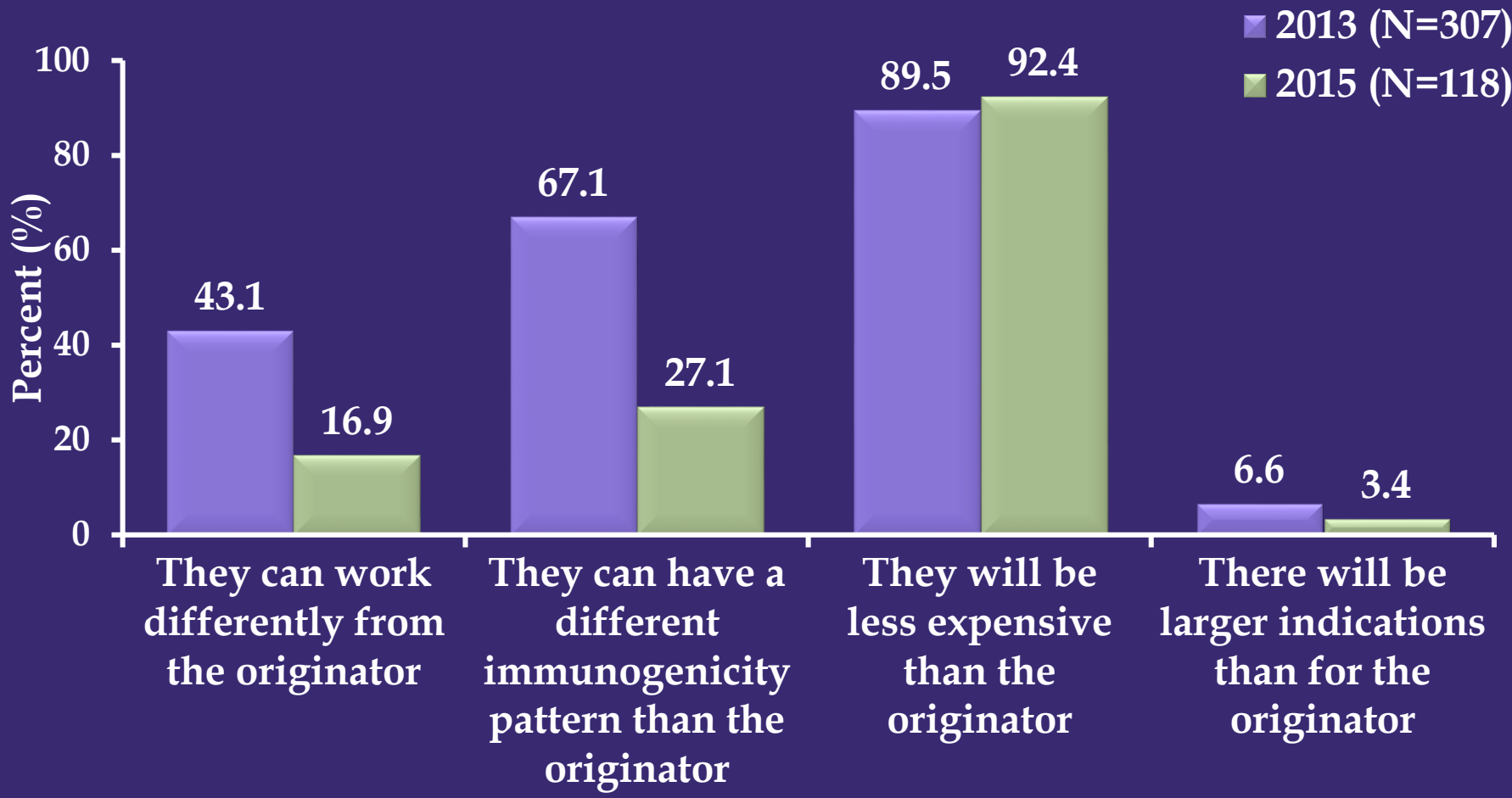
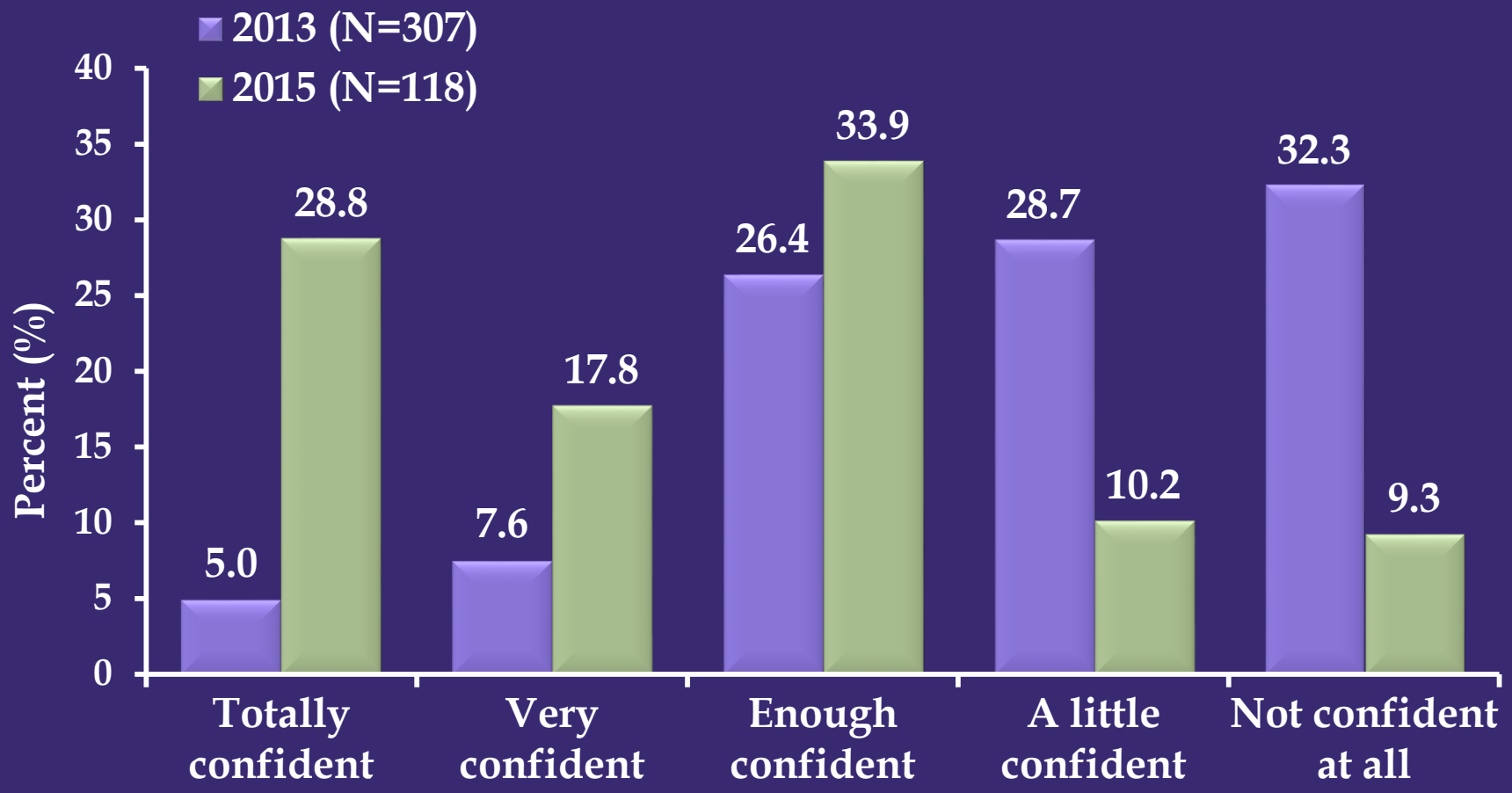
ECCO survey on biosimilars

Advantages and issues with biosimilars



Danese *et al. J Crohns Colitis* April 2016. Manuscript Doi:10.1093/ecco-jcc/jjw090

ECCO survey on biosimilars



Danese *et al. J Crohns Colitis* April 2016. Manuscript Doi:10.1093/ecco-jcc/jjw090

Κλινικές μελέτες σε ΙΦΝΕ όπου μελετήθηκε η μετάβαση σε CT-P13 από Remicade

Study (Country)	Publication Date	Centers	Total Patients (No. Switched)	Indication/Use	Duration
Kang et al (Republic of Korea)[1]	2014	1	17 (9)	CD, UC	~52 weeks[a]
Jung et al (Republic of Korea)[2]	2015	6	110 (36)	CD, UC	54 weeks
Park et al (Republic of Korea)[3]	2015	15	173 (60)	CD, FCD, UC	30 weeks
PROSIT-BIO (Italy)[4]	2016 (Abstract)	30	397 (93)	CD, UC	26 weeks[a]
Bettey et al (United Kingdom)[5]	2016 (Abstract)	1	134 (134)	IBD	Not stated
Kolar et al (Czech Republic)[6]	2016 (Abstract)	1	74 (74)	CD, UC	24 weeks
Smits et al (Netherlands)[7]	2016	1	83 (83)	CD, UC, unclassified IBD	16 weeks
Díaz Hernández et al (Spain)[8]	2016 (Abstract)	1	72 (72)	CD, UC	26 weeks[a]

[a]Calculated from reported numbers.

1. Kang YS, et al. *Dig Dis Sci*. 2015;60(4):951-956. **2.** Jung YS, et al. *J Gastroenterol Hepatol*. 2015;30(12):1705-1712. **3.** Park SH, et al. *Expert Rev Gastroenterol Hepatol*. 2015;9(suppl 1):35-44. **4.** Fiorino G, et al. Presented at: 11th Congress of the European Crohn's and Colitis Organization (ECCO) 2016. Poster P544. **5.** Bettey M, et al. *J Crohns Colitis*. 2016;10:S43-S44. **6.** Kolar M, et al. Presented at: 11th Congress of the European Crohn's and Colitis Organization (ECCO) 2016. Abstract DOP032. **7.** Smits LJ, et al. *J Crohns Colitis*. 2016;pii: jjw087 [Epub ahead of print]. **8.** Díaz Hernández L, et al. Presented at: 11th Congress of the European Crohn's and Colitis Organization (ECCO) 2016. Abstract P449.

Κλινικές μελέτες σε ΙΦΝΕ όπου μελετήθηκε η μετάβαση σε CT-P13 από Remicade

Study (Country)	Publication Date	Centers	Total Patients (No. Switched)	Indication/Use	Duration
Hlavaty et al (Slovakia)[1]	2016 (Abstract)	1	25 (12)	CD, UC	~52 weeks[a]
Guerra Veloz et al (Spain)[2,3]	2016 (Abstract)	1	CD: 75 (71) UC: 40 (31)	CD, UC	26 weeks[b]
Hamanaka et al (Japan)[4]	2016 (Abstract)	1	20 (3)	CD, UC	24 weeks
Sieczkowska et al (Poland)[5]	2016 (Abstract)	Not stated	16 (16)	CD (pediatric)	Not stated
Sieczkowska et al (Poland)[6]	2016	3	39 (39)	CD,UC (pediatric)	39 weeks[b]

[a]Calculated from reported numbers.
[b]Includes case, cohort, pediatric, or immunogenicity studies.

1. Hlavaty T, et al. Presented at: 11th Congress of the European Crohn's and Colitis Organization (ECCO) 2016; Abstract P655. **2.** Guerra Veloz MF, et al. Presented at: 11th Congress of the European Crohn's and Colitis Organization (ECCO) 2016; Abstract P452. **3** Guerra Veloz MF, et al. Presented at: 11th Congress of the European Crohn's and Colitis Organization (ECCO) 2016; Abstract P600. **4.** Hamanaka S, et al. Presented at: 11th Congress of the European Crohn's and Colitis Organization (ECCO) 2016; Abstract P329. **5.** Sieczkowska J, et al. Presented at: 11th Congress of the European Crohn's and Colitis Organization (ECCO) 2016; Abstract P417. **6.** Sieczkowska J, et al. J Crohns Colitis. 2016;10(2):127-132.

Κλινικές μελέτες σε εξέλιξη σε ΙΦΝΕ στις οποίες μελετειται η μετάβαση σε CT-P13 από Remicade

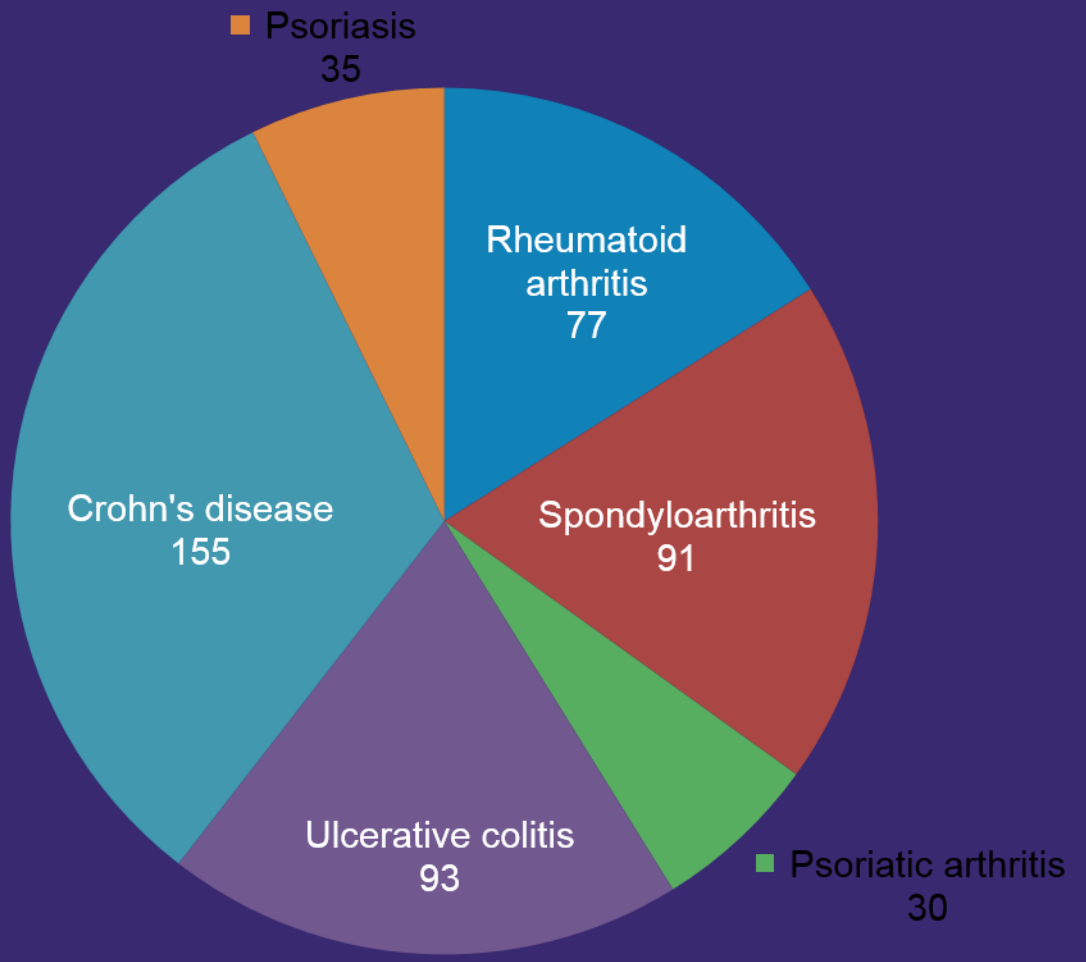
ει Study (Country)	Publication Date	Centers	Total Patients (No. Switched)	Indication/Use	Duration
CONNECT-IBD (Europe)[1]	Ongoing (Planned June 2019)	128	3300 (Estimated)	IBD, CD, UC	104 weeks[a]
CT-P13 3.4 (International)[2]	Ongoing (Planned February 2017)	~100	~214	CD	54 weeks
NOR-SWITCH[3] (Norway)	Ongoing (Planned January 2017)	30	500 (Estimated)	AS, CD, PsA, PsO, RA, UC	52 weeks

[a]Calculated from reported numbers.

1. Post-marketing use of Inflectra (infliximab) for standard of care treatment of inflammatory bowel disease (CONNECT-IBD). ClinicalTrials.gov. Last updated: March 28, 2016. https://clinicaltrials.gov/ct2/show/NCT02539368?term=NCT02539368&rank=1. Accessed April 11, 2016. **2.** Study CT-P13 3.4. Protocol version 2.2. February 10, 2015. Data on file. Celltrion, Inc., Incheon, South Korea; 2015:10-17. **3.** The NOR-SWITCH Study (NOR-SWITCH). Clinicaltrialsregister.eu. https://www.clinicaltrialsregister.eu/ctr-search/trial/2014-002056-40/NO. Last updated: June 13, 2015. Accessed June 9, 2016.

Diagnosis Distribution (Number of Patients)

NOR-SWITCH



Primary Endpoint:

Disease Worsening Across Indications

	INX (N=202)	CT-P13 (N=206)	Adjusted Rate Difference (95% CI)
Disease worsening (all indications)*	53 (26.2%)	61 (29.6%)	-4.4 (-12.7–3.9)

The authors concluded that switch from INX to CT-P13 was not inferior to continued treatment with INX

Antidrug Antibodies (ADAs)

	INX (N=241)	CT-P13 (N=240)
Incidence of ADAs	17 (7.1%)	19 (7.9%)

Trough drug levels and frequencies of adverse events, including infusion reactions, were similar between INX and CT-P13

Cross-immunogenicity: antibodies to infliximab in Remicade-treated patients with IBD similarly recognise the biosimilar Remsima

Shomron Ben-Horin,[1] Miri Yavzori,[1] Itai Benhar,[2] Ella Fudim,[1] Orit Picard,[1] Bella Ungar,[1] SooYoung Lee,[3] SungHwan Kim,[3] Rami Eliakim,[1] Yehuda Chowers[4]

Conclusions Anti-Remicade antibodies in patients with IBD recognise and functionally inhibit Remsima to a similar degree, suggesting similar immunogenicity and shared immunodominant epitopes on these two infliximab agents. In contrast, anti-adalimumab antibodies do not cross-react with Remsima or Remicade.

Ben Horin S et al, Gut 2015;in press

Harmonization of Infliximab and Anti-Infliximab Assays Facilitates the Comparison Between Originators and Biosimilars in Clinical Samples

Ann Gils, PharmD, PhD, Thomas Van Stappen, PharmD,* Erwin Dreesen, PharmD,* Ruth Storme, PharmD,* Séverine Vermeire, MD, PhD,† and Paul J. Declerck, PharmD, PhD**

Conclusions: The assay for therapeutic drug monitoring of Remicade can also be used to determine Remsima and Inflectra concentrations. Anti-drug antibody assays for biosimilars were developed. Anti-Remicade antibodies cross-react with infliximab biosimilars and reveal consistent negative/positive anti-drug antibody responses and highly correlated titers.

Gils A et al, IBD 2016;22:969-975