ΣΕΙΡΑ ΔΙΑΔΙΚΤΥΑΚΩΝ ΕΚΠΑΙΔΕΥΤΙΚΩΝ ΣΕΜΙΝΑΡΙΩΝ (WEBINARS)

ΕΛΛΗΝΙΚΗ ΡΕΥΜΑΤΟΛΟΓΙΚΗ ΕΤΑΙΡΕΙΑ
& ΕΠΑΓΓΕΛΜΑΤΙΚΗ ΕΝΩΣΗ
ΡΕΥΜΑΤΟΛΟΓΩΝ ΕΛΛΑΔΟΣ
Έτος Ιδρύσεως 1960

Εξελίξεις στη Ρευματολογία
ΙΟΥΝΙΟΣ- ΝΟΕΜΒΡΙΟΣ 2020
2. ΒΙΟ-ΟΜΟΕΙΔΗ ΣΤΙΣ ΡΕΥΜΑΤΙΚΕΣ ΠΑΘΗΣΕΙΣ

ΤΡΙΤΗ
22 ΣΕΠΤΕΜΒΡΙΟΥ
2020
19.30 - 20.30

Βιο-ομοειδή: Κλινική εμπειρία και προοπτικές

Αλέξιος Ηλιόπουλος

Ρευματολογικό Τμήμα ΝΙΜΤΣ

Σύγκρουση συμφερόντων
Conflict of interest

Δεν υπάρχει σύγκρουση συμφερόντων για την παρουσίαση

Περίγραμμα της παρουσίασης

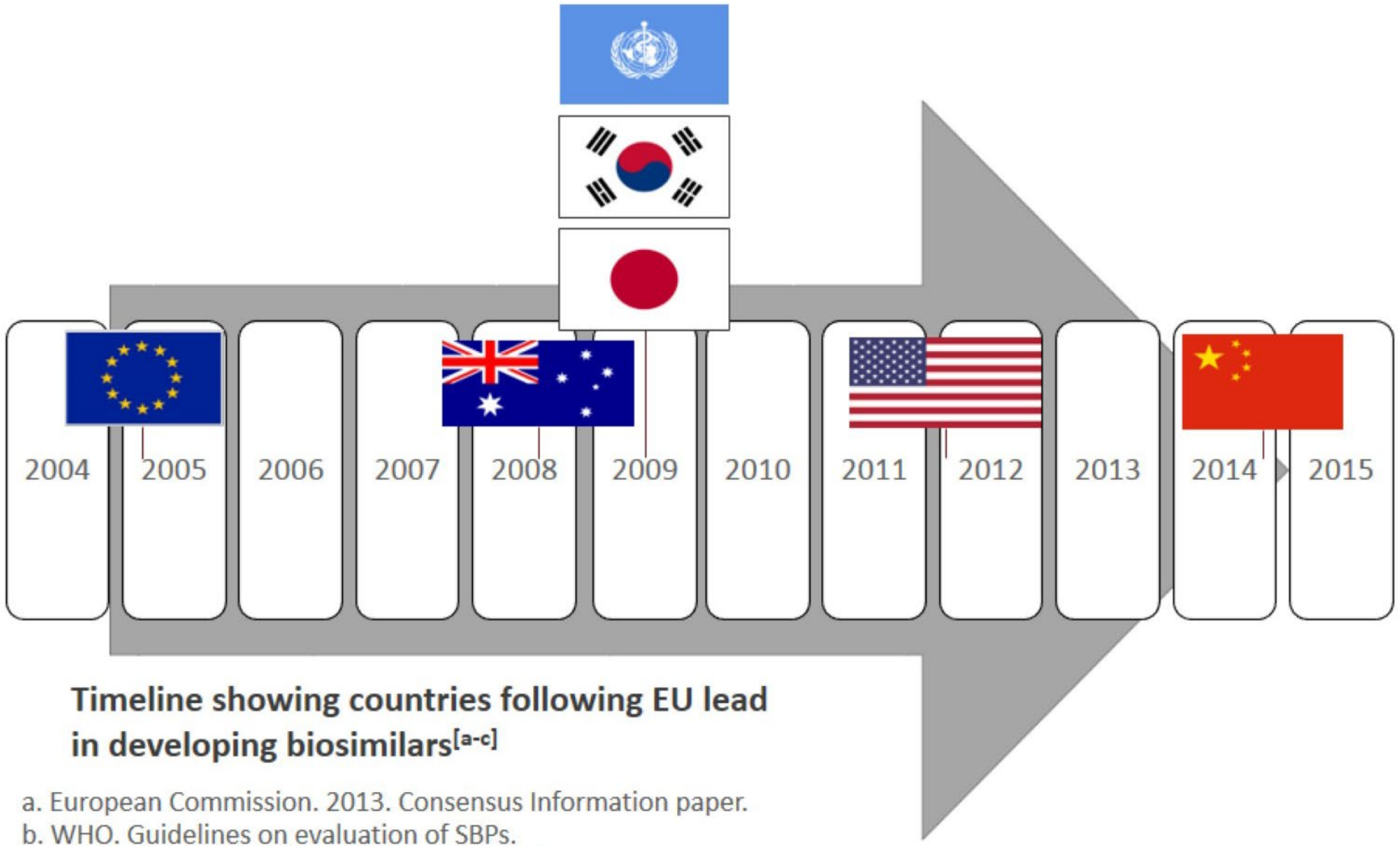
Βιοομοειδή:

- **Σύντομη ιστορική αναδρομή, βιοομοειδή και αρχικά φάρμακα**
- **Το CT-P13 σαν μοντέλο εισόδου και παραμονής αντι-TNF βιοομοειδούς στην κλινική πράξη**
- **Δεδομένα από επόμενα μέχρι τώρα βιοομοειδή, έναντι αντι-TNF παράγοντα και Β λεμφοκυττάρου**
- **Ζητήματα ανταλλαξιμότητας, ιατρικής και μη**

Σύντομη ιστορική αναδρομή

- Οι βιολογικοί παράγοντες τα πρώτα έτη από την είσοδό τους στην κλινική πράξη είχαν ήδη επιφέρει θεραπευτική επανάσταση στη Ρευματολογία
- Όμως το κόστος κατά την πρώτη πενταετία της κλινικής εφαρμογής τους ήταν εξαιρετικά υψηλό, σε επίπεδο 20-25.000 ευρώ ετησίως ανά ασθενή, για τους 3 πρώτους αντι-TNF παράγοντες, infliximab, etanercept και adalimumab. Το αντίστοιχο κόστος στις ΗΠΑ την ίδια εποχή έφθανε τα 30-40 χιλιάδες δολάρια
- Με τα δεδομένα αυτά η φαρμακευτική βιομηχανία παράλληλα με την ανάπτυξη νεότερων βιολογικών παραγόντων ξεκίνησε έρευνα δημιουργίας βιοομοειδών και όχι γενοσήμων, αφού πρόκειται για εξαρχής κατασκευή νέου φαρμάκου και όχι για αντιγραφή χημικού τύπου
- ..the projected cost savings that can be achieved over the next 10 years by use of biosimilars has been estimated to range from a conservative low of $3.6 billion to a high of $71 billion US dollars, Braun J, Immunotherapy 2015;7(2):73-87

Το ιστορικό της ανάπτυξης βιοομοειδών

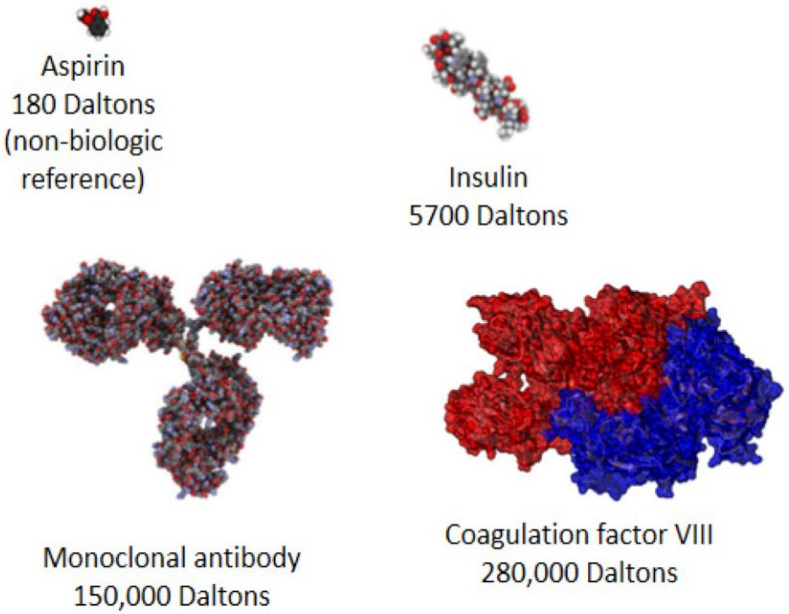


Timeline showing countries following EU lead in developing biosimilars[a-c]

a. European Commission. 2013. Consensus Information paper.
b. WHO. Guidelines on evaluation of SBPs.
c. Generics and Biosimilars Initiative. Biosimilars.

Βιοομοειδή και όχι γενόσημα

- **Ένα βιολογικό προϊόν που είναι παρόμοιο όσον αφορά στην ποιότητα, την ασφάλεια και την αποτελεσματικότητα, με το βιοθεραπευτικό προϊόν αναφοράς που έχει ήδη άδεια**
- **Πρόκειται όχι για αντιγραφή χημικού τύπου, αλλά για δημιουργία εξαρχής μιας νέας σύνθετης πρωτεϊνικής τεταρτοταγούς δομής, η οποία να μην είναι ακριβώς όμοια, αλλά να έχει παρόμοιες ιδιότητες με το αρχικό φάρμακο**
- **Τα βιολογικά μόρια είναι σημαντικά μεγαλύτερα και πιο πολύπλοκα σε σύγκριση με τα φάρμακα με μικρά μόρια**



Ένα μόριο μονοκλωνικού αντισώματος είναι περισσότερο από 1000 φορές μεγαλύτερο από ένα μόριο ασπιρίνης

A Biosimilar IS NOT a Generic

Generic
(chemically synthesized "copy")

Phase 1 bioequivalence

How identical structure

Equivalent efficacy/safety

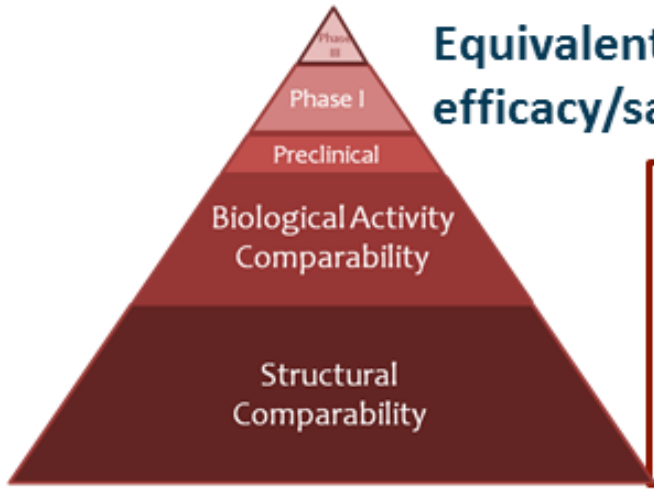
Abridged dossier
Quality + phase 1
0.5-1.5 years
0.5-1.5 MM €

Identical active ingredient

Based on originator's dossier

Conceptual analogy (legal basis)

Biosimilar
(biologic nedicine replica)



Equivalent efficacy/safety

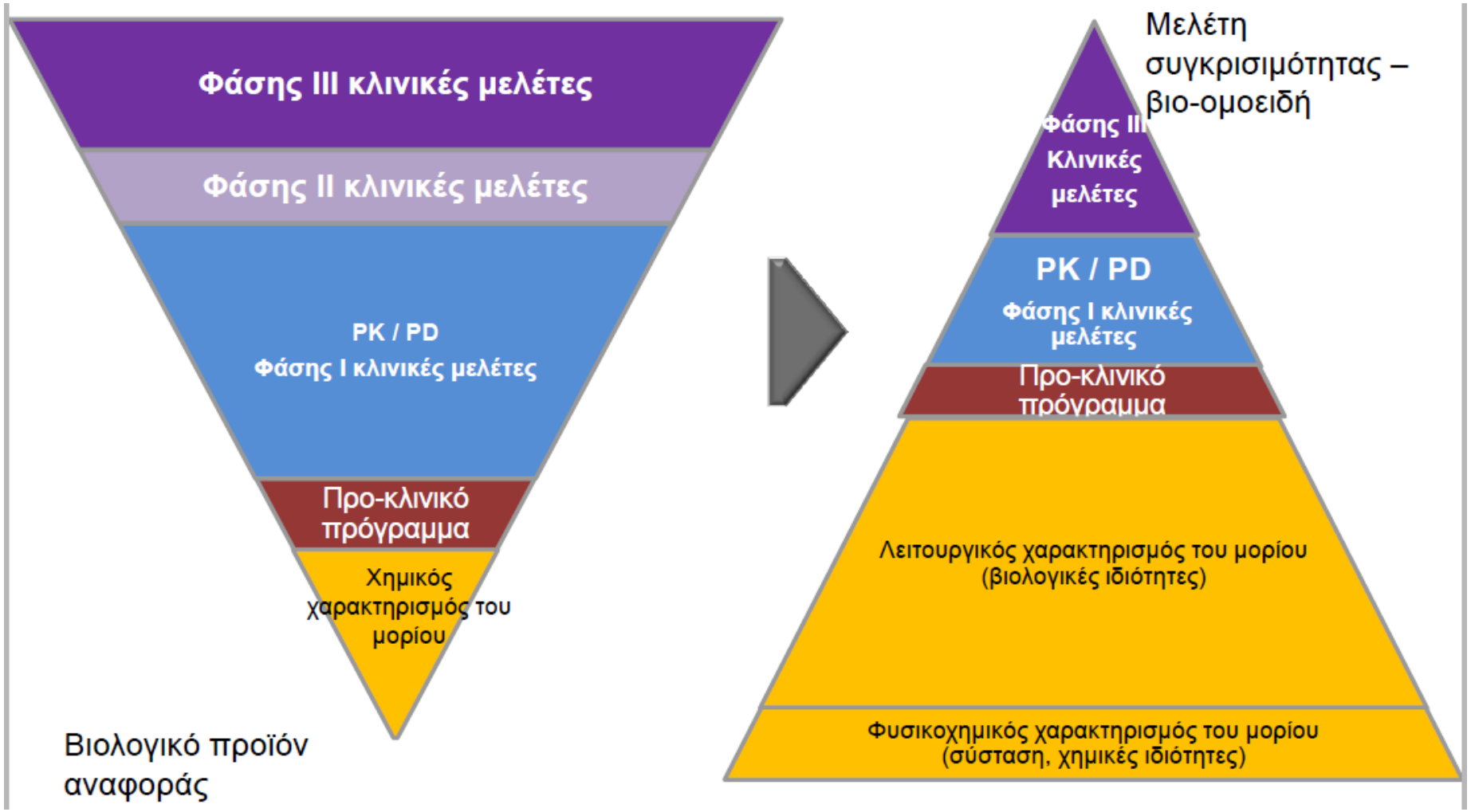
Customized dossier
Clinical and nonclinical
6-12 years
40-200 MM €

Essentially same active ingredient

Based on originator's dossier

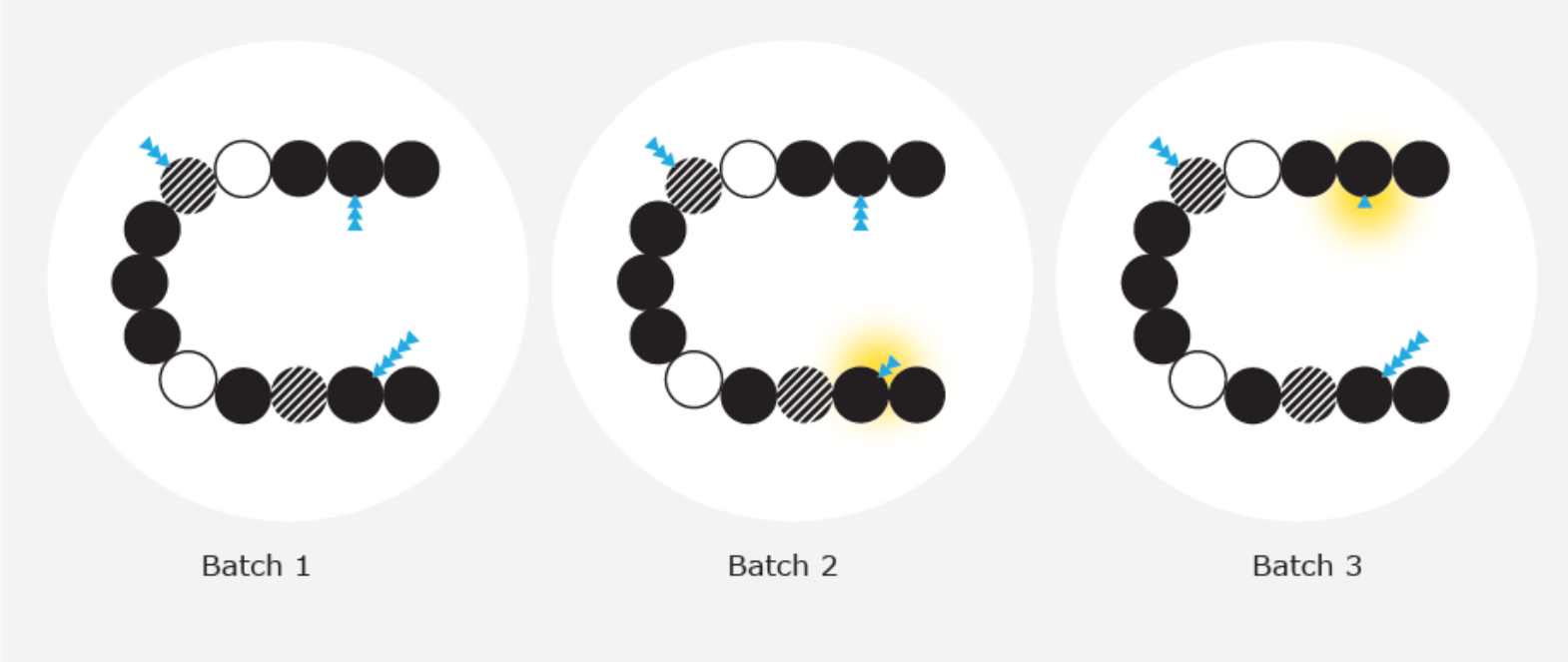
Fernardo de Mora, medscape.com

Στάδια ανάπτυξης του αρχικού και του βιοομοειδούς φαρμάκου



Στάδιο 1 – Σύγκριση Ποιότητας
Στάδιο 2 – Μη κλινική σύγκριση
Στάδιο 3 – Κλινική σύγκριση

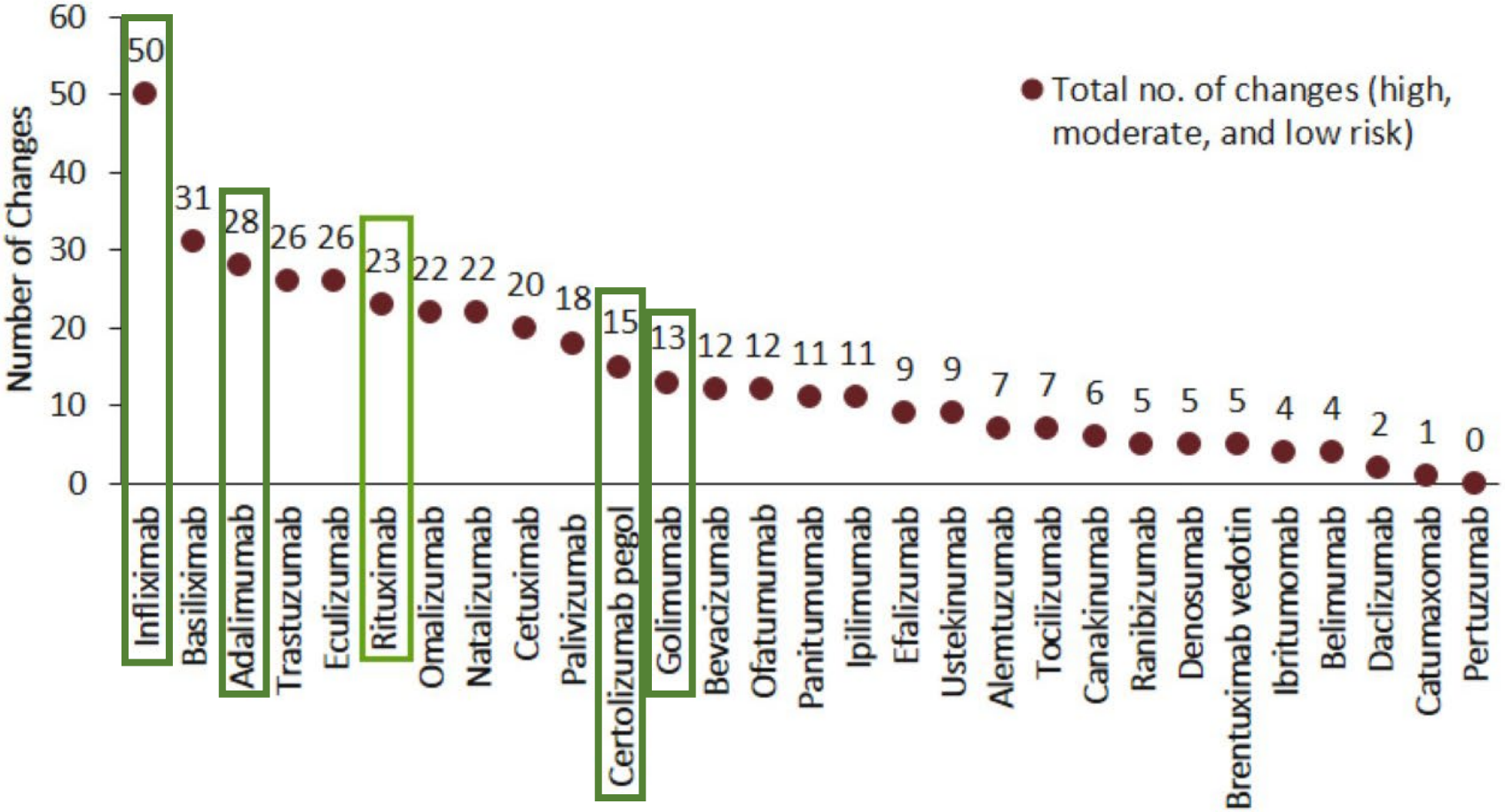
“no clinically meaningful differences”



Διαδοχικές εκδόσεις του ίδιου βιολογικού προϊόντος μπορεί να δείχνουν μικρό βαθμό διαφοροποίησης (κίτρινη σκίαση) σε αποδεκτό εύρος, για παράδειγμα στη γλυκοζυλίωση (παράγωγα σακχάρων προσκολλημένα σε πρωτεΐνη, μπλε τρίγωνα). Η αλληλουχία αμινοξέων (κύκλοι) και η βιολογική δράση της πρωτεΐνης παραμένουν ίδιες σε όλες τις εκδόσεις, ακόμη και όταν υπάρχουν μικρές διαφορές στις αλύσους σακχάρων.

Biosimilars in the EU, EMA

Οι βιολογικοί παράγοντες έχουν υποστεί πολλές μεταβολές στο αρχικό μόριο, που δεν έχουν όμως μεταβάλλει σημαντικά την δράση τους



“A reference biomedicine, having undergone several modifications since its commercialization, can be considered a biosimilar of itself” **Jean-David Cohen, Clinical Rheumatology (2020) 39:2251–2254**

Vezér B, et al. *Curr Med Res Opin.* 2016;32:829-34.

Βιοομοειδή και ρυθμιστικές αρχές

	EMA	WHO	USA
Preclinical data	Target binding; signal transduction, functional activity/viability of cells of relevance. If in vitro comparability is satisfactory, animal studies may not be required	Receptor-binding or cell-based assays; relevant biologic/PD activity, toxicity	Structural analyses, functional assays; animal toxicity assessments, PK/PD, immunogenicity (unless determined not necessary by FDA)
Clinical trials	Comparability demonstrated in stepwise process using PK, PD (if feasible), followed by clinical efficacy and safety trials	PK, PD, (confirmatory PK/PD), efficacy, and safety	Study or studies including assessments of immunogenicity and PK or PD
Naming	Commercial name, appearance, and packaging should differ; INN should be the same for related biosimilars	Changes are being considered to the current policy of using INN	Draft guidance proposes that all biologics be given a 4-letter suffix to the INN
Pharmacovigilance	Risk management pharmacovigilance plan must be submitted; clinical safety monitored closely after marketing authorization	Pharmacovigilance plan submitted with marketing authorization application; describe planned post-marketing activities	Any risk evaluation and mitigation strategy for the reference product applies. Post-marketing studies or additional clinical trials could be mandated

Mysler E, et al. *Rheumatol Int*. 2016;36:613-625.

International Nonproprietary Names (INN) identify pharmaceutical substances or active pharmaceutical ingredients

U.S. FOOD & DRUG ADMINISTRATION

Biosimilar Product Regulatory Review and Approval

Περί Extrapolation (Παρέκτασης)

The concept of extrapolation is based on:

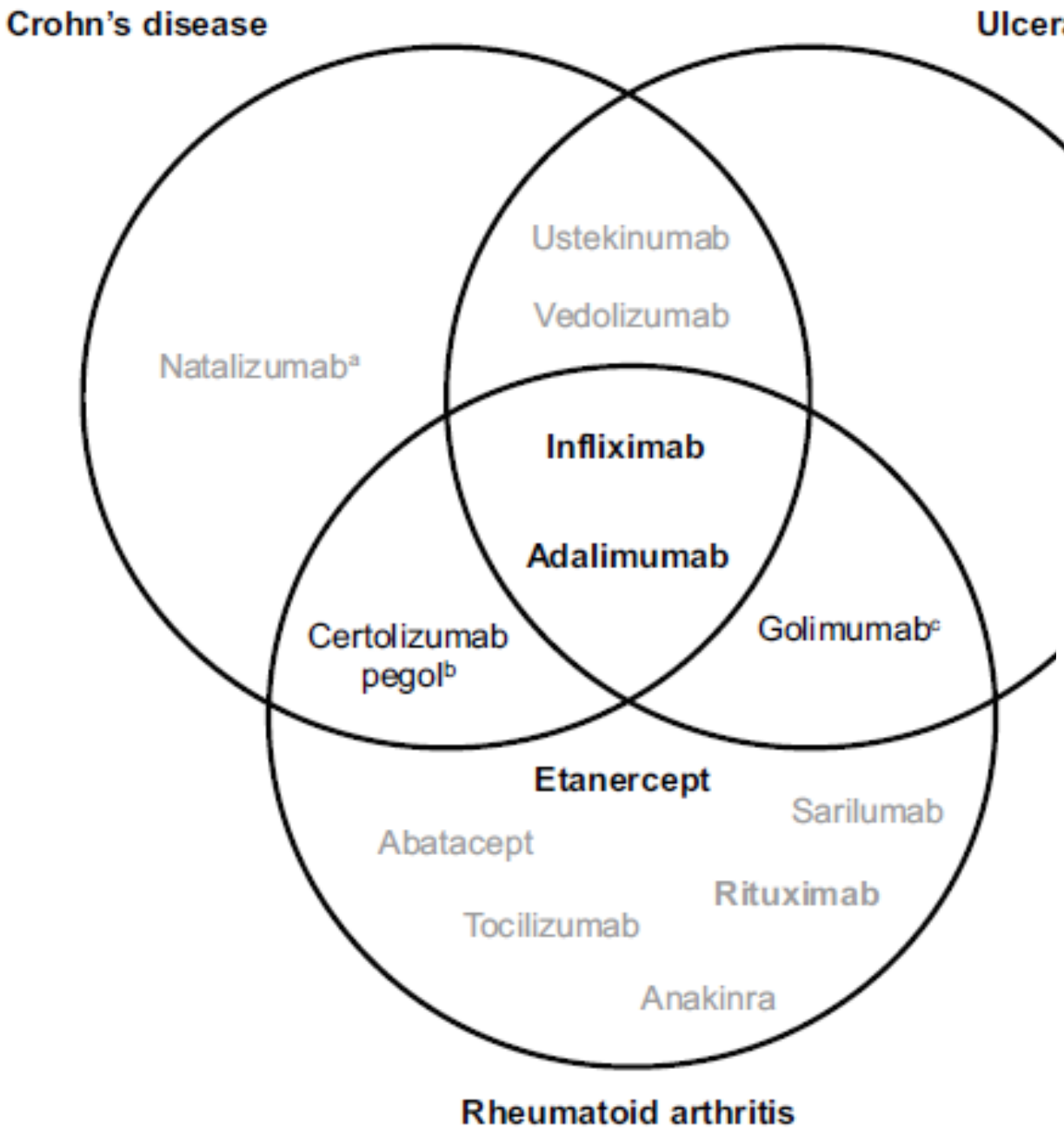
- All available data and information in the biosimilar application
- FDA's previous finding of safety and efficacy for other approved indications for the reference product
- Knowledge and consideration of various scientific factors for each indication

«Can a biosimilar be approved for an indication that is approved for the reference product even if the biosimilar is not directly studied in that indication?

Yes, a biosimilar product may be approved for an indication without direct studies of the biosimilar in that indication. If the total evidence in the biosimilar application supports a demonstration of biosimilarity for at least one of the reference product's indications, then it is possible for the biosimilar manufacturer to use data and information to scientifically justify approval for other indications that were not directly studied by the biosimilar manufacturer. This concept is called "extrapolation" and is critical to the goals of an abbreviated pathway—improving access and options at a potentially lower cost.»

www.fda.gov

Το μέλλον των βιοομοειδών



Biologics licensed by the FDA and/or EMA for the treatment of RA and/or IBD as of 25 November 2019 (references are provided in Table S2 in the electronic supplementary material). TNF inhibitors are shown in black; biologics with other targets are shown in gray. For biologics shown in bold, biosimilars have been licensed by the FDA and/or the EMA in relevant indications. A Licensed by the FDA only. B Licensed by the FDA only for the treatment of Crohn's disease. C The intravenous form of golimumab (Simponi Aria®) is licensed by the FDA only, for the treatment of RA only.

Kim H, Drugs (2020) 80:99–113

Anti-TNF Biosimilars Approved in EU

Adalimumab	Etanercept	Infliximab
• Amgevita • Cyltezo • Halimatoz • Hefiya • Hulio • Hyrimoz • Idacio • Imraldi • Solymbic	• Benepali • Erelzi	• Inflectra • Flixabi • Remsima • Zessly

EMA website. List of approved biosimilars of adalimumab, etanercept and infliximab.

Το CT-P13 σαν μοντέλο εισόδου και παραμονής αντι-TNF βιοομοειδούς στην κλινική πράξη

Κλινικές μελέτες στις οποίες εξετάστηκε η μετάβαση από Remicade σε CT-P13 στα ρευματικά νοσήματα

	Μελέτη (Χώρα)	Με την υποστήριξη της Celltrion/Pfizer	Ημερομηνία ολοκλήρωσης ή δημοσίευσης	Κέντρα	Συνολικός αριθμός ασθενών (Αρ. μεταταχθέντων)	Ένδειξη/Χρήση	Διάρκεια
	Παράταση μελέτης PLANETRA[1] (διεθνής)	HSP/PFE	Ιούλιος 2013	69	302 (144)	ΡΑ	48 εβδ
	Παράταση μελέτης PLANETAS[2] (διεθνής)	HSP/PFE	Ιούνιος 2013	40	174 (86)	ΑΣ	48 εβδ
	Μελέτη NOR-SWITCH[3] (Νορβηγία)	Όχι	Ιούνιος 2017	40	481 (240)	ΑΣ, ΝC, ΨΑ, Ψ, ΡΑ, ΕΚ	52 εβδ

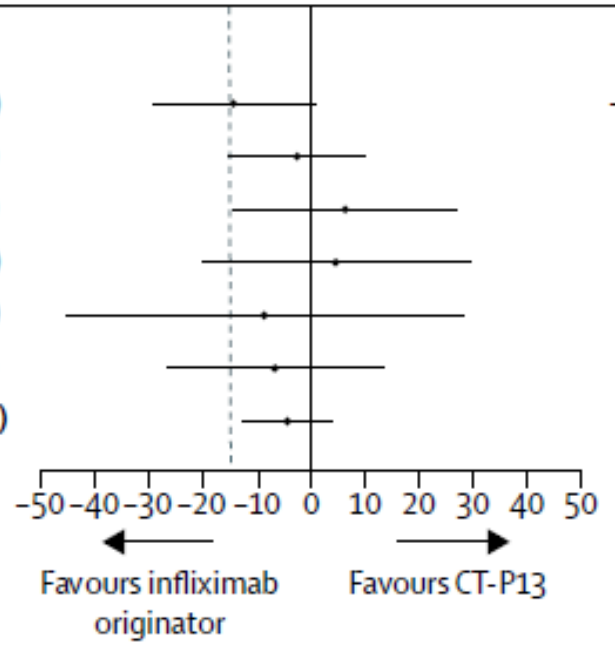
1. Yoo DH et al. *Ann Rheum Dis.* 2017;76(2):355-363. 2. Park W et al. *Ann Rheum Dis.* 2017;76(2):346-354. 3. Jørgensen K et al. Lancet. 2017;389(10086):2304-2316

Η μελέτη NOR-SWITCH

Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial

- Τυχαιοποιημένη, διπλά τυφλή
- 40 νοσοκομεία στη Νορβηγία
- 408 ασθενείς με παθήσεις σε θεραπεία με infliximab, σε 206 η αγωγή άλλαξε σε CT-P13

	Infliximab originator n=202	CT-P13 n=206	Risk difference (95% CI)
Diagnosis			
Crohn's disease	14 (21·2%)	23 (36·5%)	−14·3% (−29·3 to 0·7)
Ulcerative colitis	3 (9·1%)	5 (11·9%)	−2·6% (−15·2 to 10·0)
Spondyloarthritis	17 (39·5%)	14 (33·3%)	6·3% (−14·5 to 27·2)
Rheumatoid arthritis	11 (36·7%)	9 (30·0%)	4·5% (−20·3 to 29·3)
Psoriatic arthritis	7 (53·8%)	8 (61·5%)	−8·7% (−45·4 to 28·1)
Psoriasis	1 (5·9%)	2 (12·5%)	−6·7% (−26·7 to 13·2)
Overall	**53 (26·2%)**	**61 (29·6%)**	**−4·4% (−12·7 to 13·2)**



Interpretation: The NOR-SWITCH trial showed that switching from infliximab originator to CT-P13 was not inferior to continued treatment with infliximab originator according to a prespecified non-inferiority margin of 15%. The study was not powered to show non-inferiority in individual diseases.

Jørgensen KK, Lancet 2017;389:2304-2316

JIM Original Article

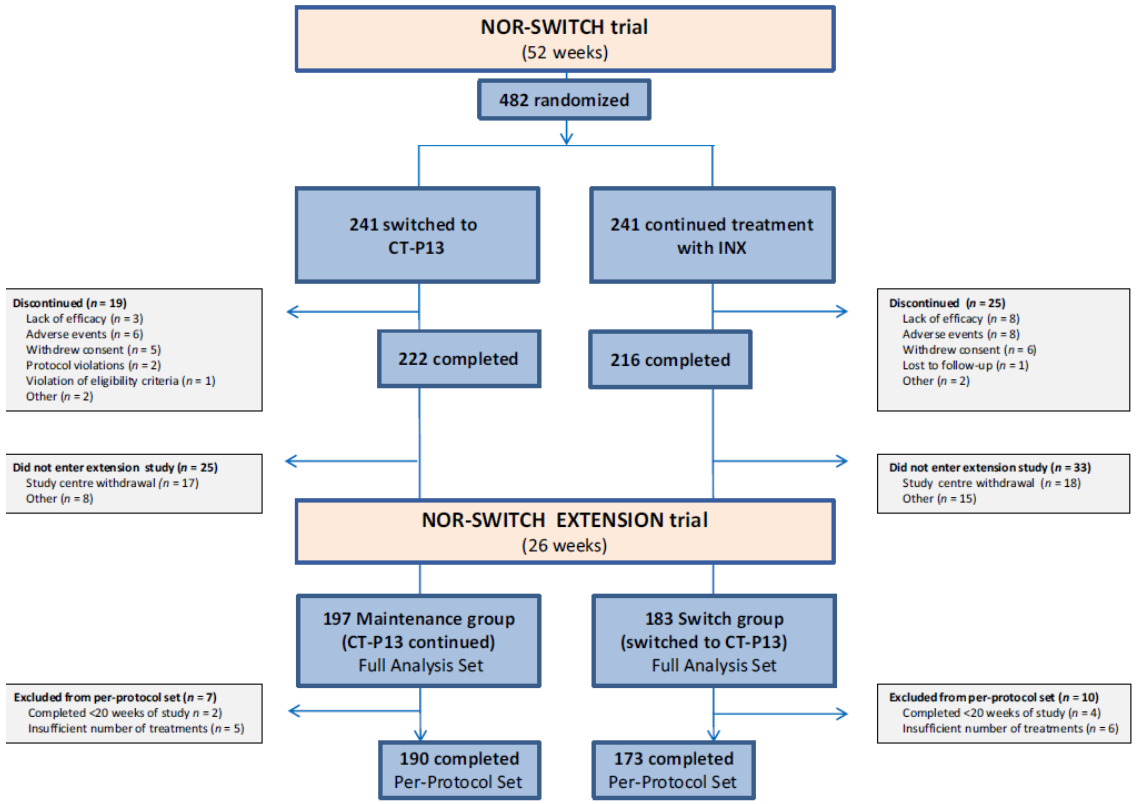
Click here to view the Editorial Comment by Dr. Kay

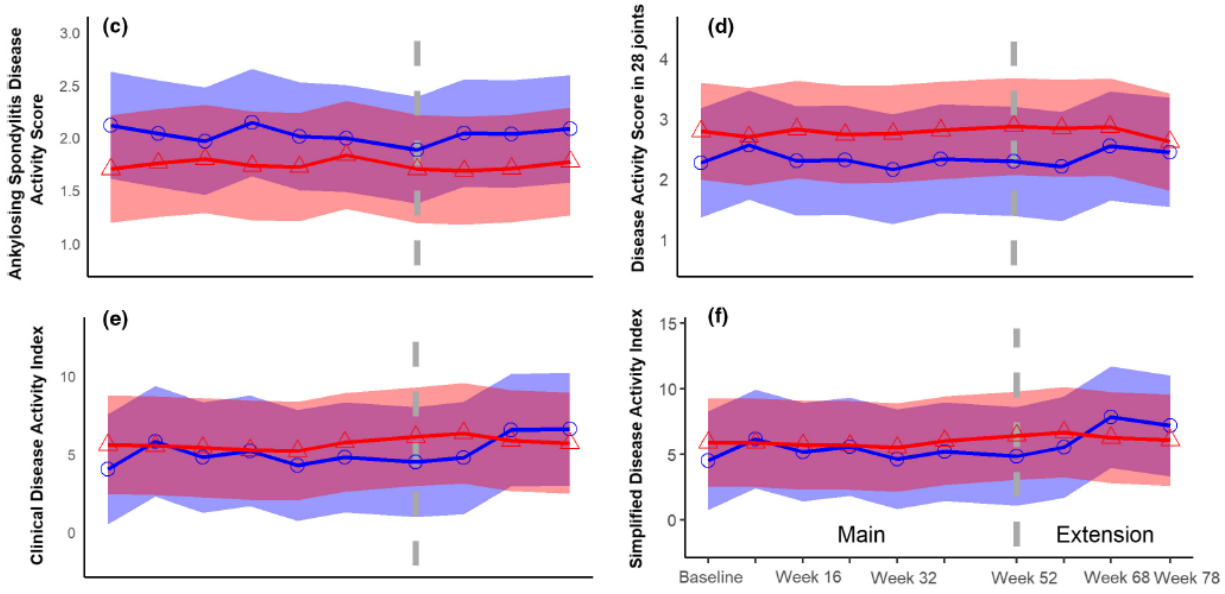
doi: 10.1111/joim.12880

Long-term efficacy and safety of biosimilar infliximab (CT-P13) after switching from originator infliximab: open-label extension of the NOR-SWITCH trial

Επέκταση της μελέτης NOR-SWITCH με αλλαγή όλων των ασθενών στο CT-P13

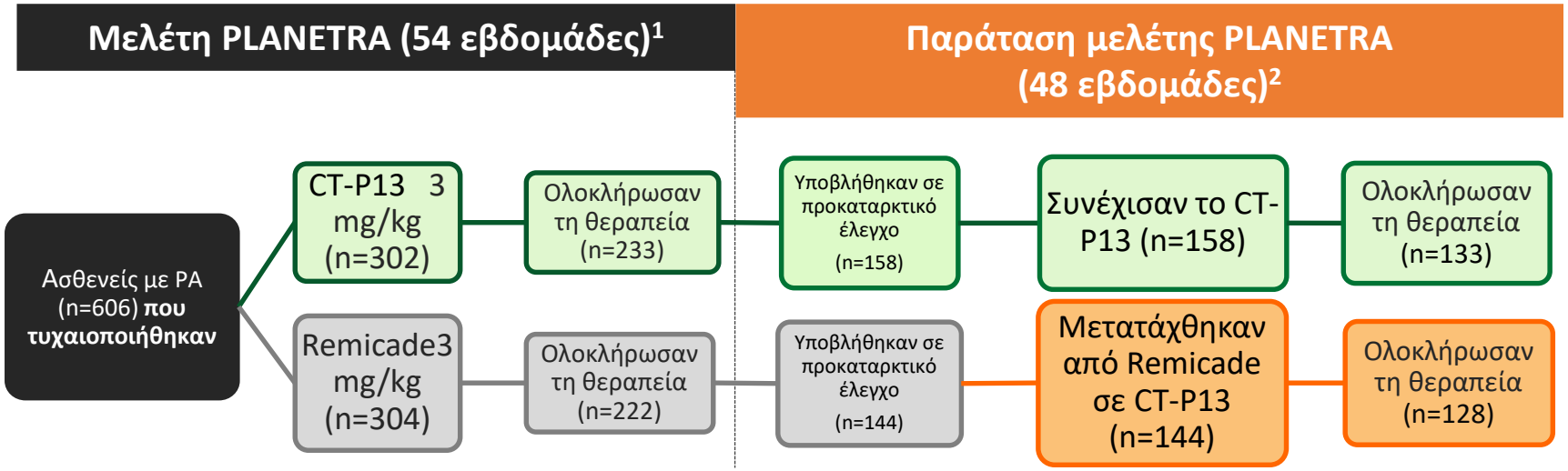
Patients were recruited from 24 Norwegian hospitals, 380 of 438 patients who completed the main study: 197 in the maintenance group and 183 in the switch group





Goll GL, J Intern Med. 2019;285(6):653-669

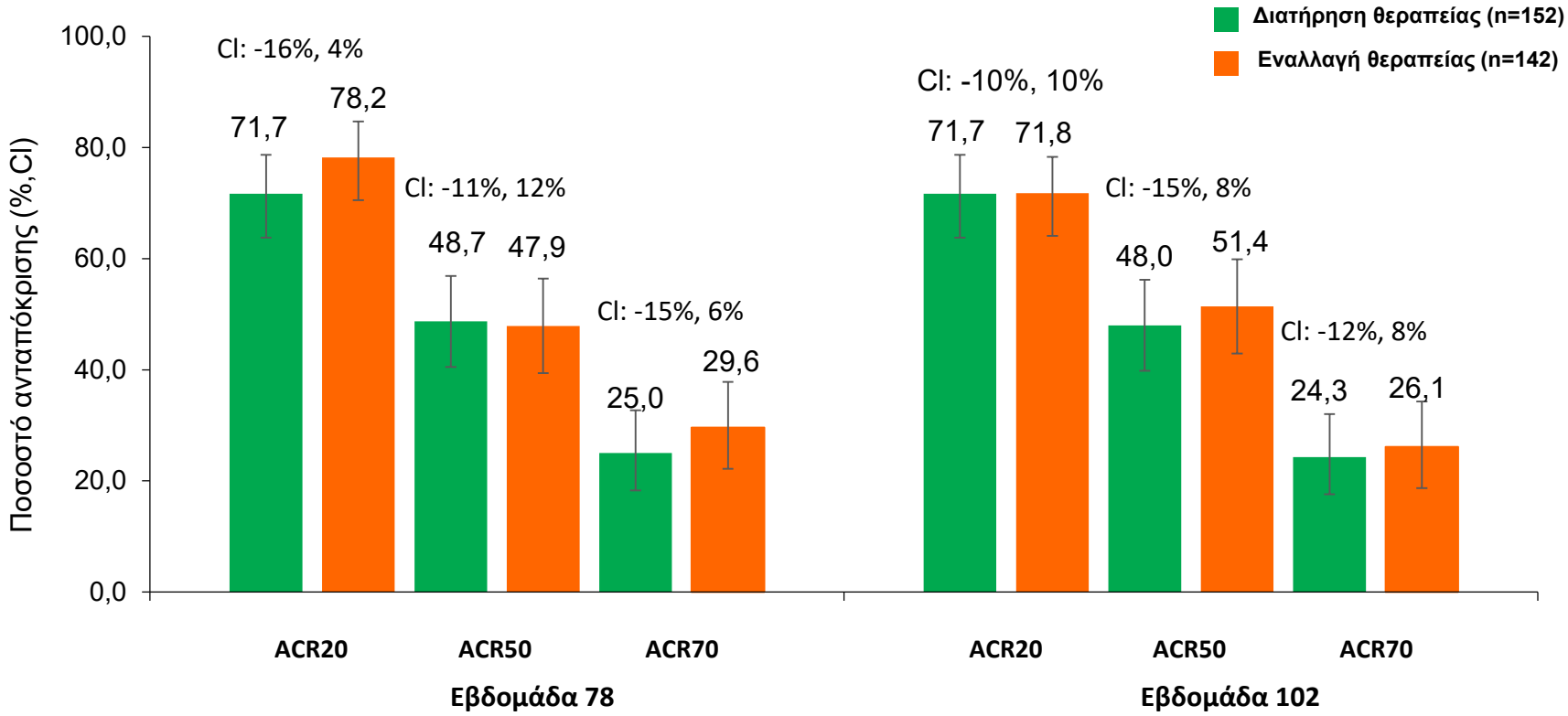
Παράταση μελέτης PLANETRA



Επιλέξιμοι ασθενείς από τη μελέτη PLANETRA εισήχθησαν σε μια μελέτη παράτασης 48 εβδομάδων για την αξιολόγηση της αποτελεσματικότητας και της ασφάλειας της μετάβασης από Remicade σε CT-P13 (ομάδα εναλλαγής θεραπείας) σε σχέση με τη διατήρηση της θεραπείας με CT-P13 (ομάδα διατήρησης θεραπείας)[2]

1. Yoo DH et al. *Arthritis Res Ther.* 2016l18(1):82.
2. Yoo DH et al. *Ann Rheum Dis.* 2017;76(2):355-363.

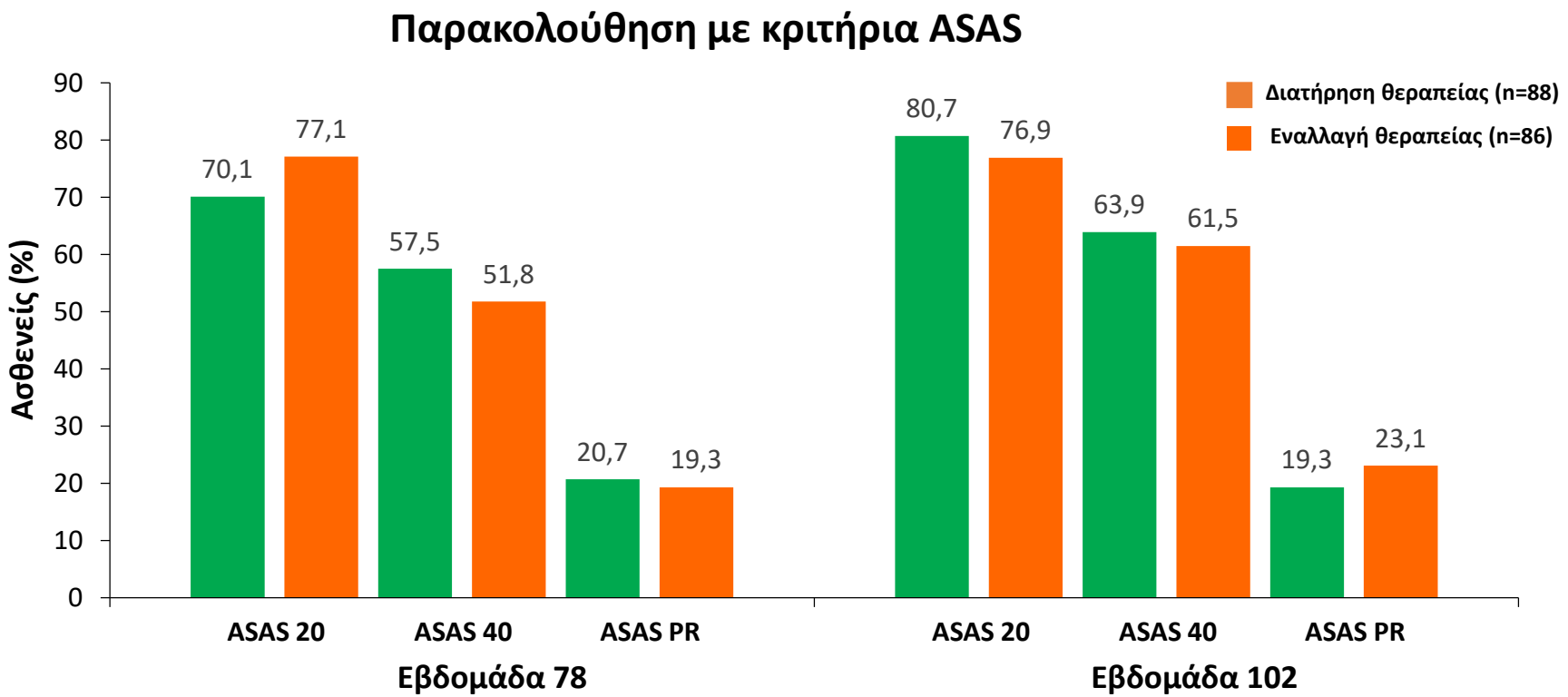
Παράταση μελέτης PLANETRA: Ποσοστά κλινικής ανταπόκρισης



Οι ανταποκρίσεις ACR20, ACR50 και ACR70 δεν διέφεραν σημαντικά μεταξύ των ομάδων διατήρησης και εναλλαγής θεραπείας τις εβδομάδες 78 και 102

Yoo DH et al. *Ann Rheum Dis.* 2017;76(2):355-363

Παράταση μελέτης PLANETAS: Ποσοστά κλινικής ανταπόκρισης



Οι ανταποκρίσεις ASAS 20, ASAS 40, and ASAS PR ήταν παρόμοιες μεταξύ των ομάδων διατήρησης και εναλλαγής θεραπείας τις εβδομάδες 78 και 102

Park W et al. *Ann Rheum Dis.* 2017;76(2):346-354

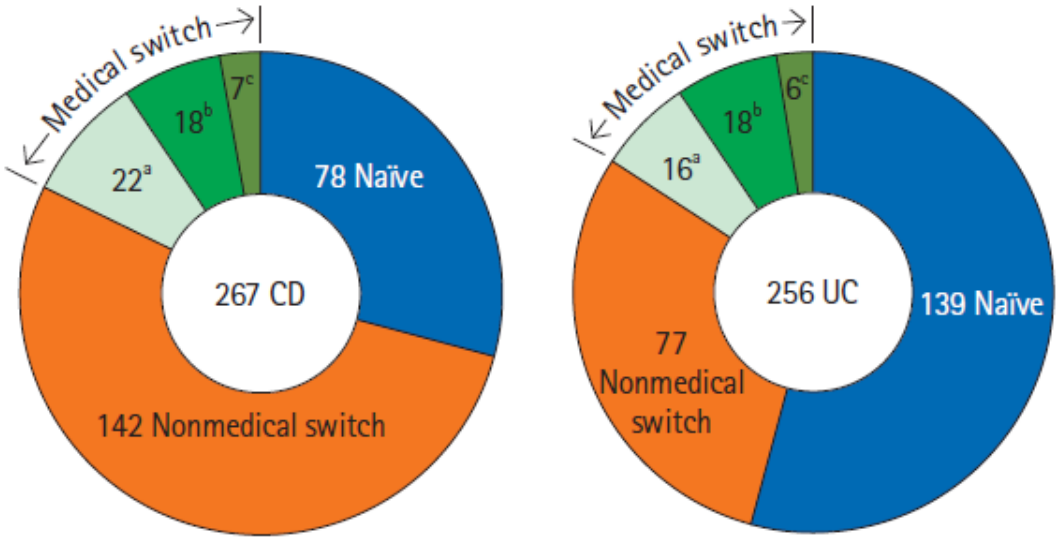
ORIGINAL ARTICLE

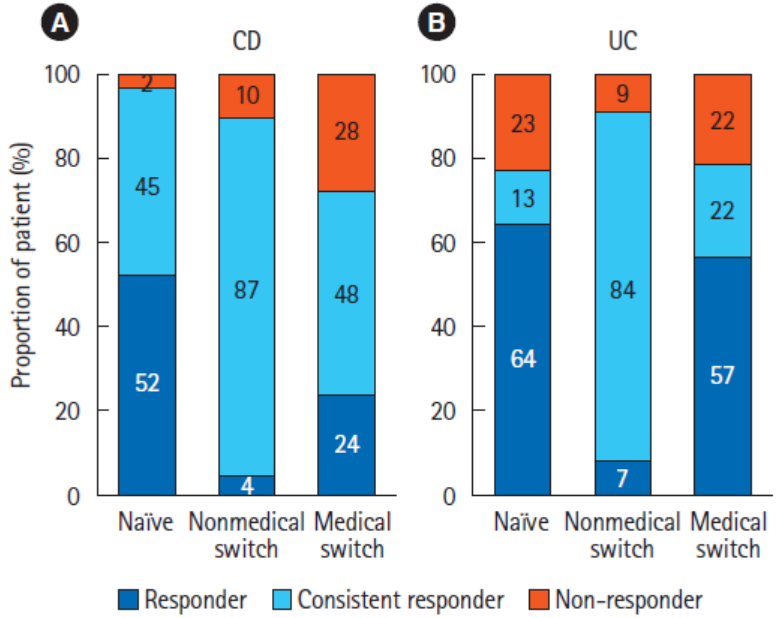
INTESTINAL RESEARCH

pISSN 1598-9100 • eISSN 2288-1956
https://doi.org/10.5217/ir.2019.00030
Intest Res 2019;17(4):504-515

Infliximab biosimilar CT-P13 is interchangeable with its originator for patients with inflammatory bowel disease in real world practice

Αλλαγή από infliximab αναφοράς σε CT-P13 για ιατρικούς και μη λόγους σε ΙΦΝΕ



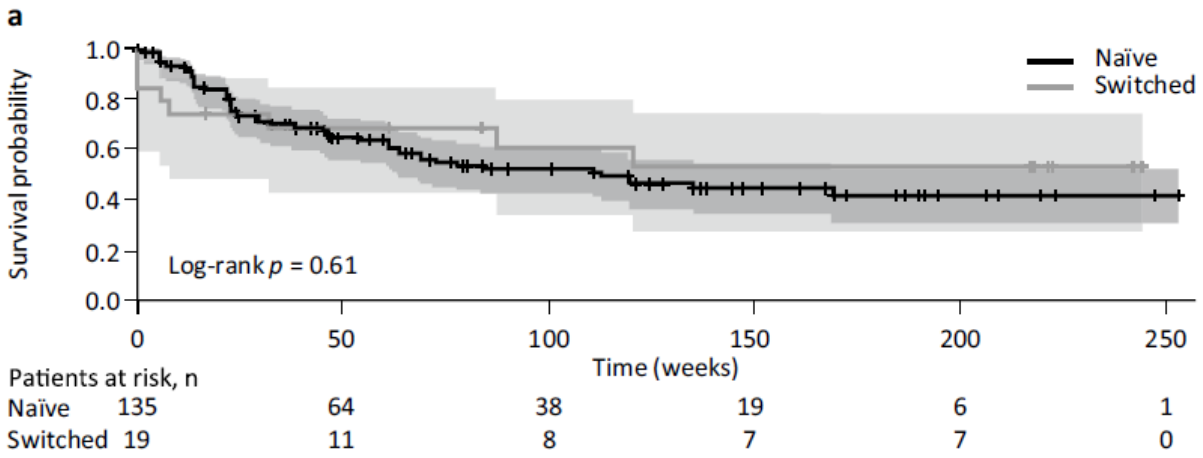


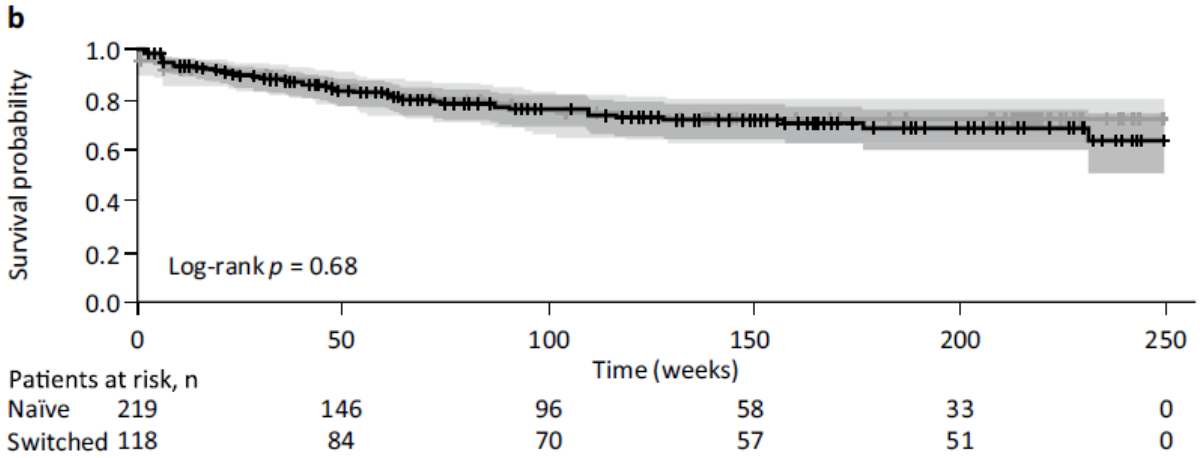
Patients were classified into 3 groups: naove patients who had no previous anti-TNF-α antibody treatment, patients switched for nonmedical reasons such as institutional policy or economic reason (nonmedical switch), and patients switched for medical reasons (medical switch). The medical switch group was further devided into 3 subgroups. aSwitching to CT-P13 from infliximab (IFX) due to adverse events or insufficient efficacy; bSwitching from adalimumab; cRetreatment with CT-P13 for relapse after discontinuation of IFX due to remission of disease.

Nakagawa T, Intest Res 2019;17:504-515

ORIGINAL RESEARCH ARTICLE

A 5-year Retrospective Analysis of Drug Survival, Safety, and Effectiveness of the Infliximab Biosimilar CT-P13 in Patients with Rheumatoid Arthritis and Ankylosing Spondylitis





CT-P13 για 5 έτη σε PA και ΑΣ

Drug survival, according to previous infliximab treatment (naove vs switched; Safety analysis group). **a** Drug survival in patients with RA. **b** Drug survival in patients with AS. The numbers of patients still receiving each drug at different time points are shown. + Indicates censored patients. Shaded areas show the 95% confidence interval.

Five-year analysis showed that long-term treatment with the infliximab biosimilar CT-P13 was safe and effective in patients with rheumatoid arthritis (RA) or ankylosing spondylitis (AS) treated under routine medical care in the Republic of Korea

T.-H. Kim, *Clin Drug Investig*. 2020;40(6):541-553

Δεδομένα αλλαγής από το αρχικό μόριο στο βιοομοειδές για τους 3 πρώτους αντι-TNF παράγοντες

NOR-SWITCH[a]	VOLTAIRE-RA[b]	EGALITY[c]
Randomized, non-inferiority trial	Randomized, parallel-arm, equivalence trial	Randomized, confirmatory efficacy and safety trial
Infliximab to biosimilar	Adalimumab to biosimilar	Etanercept to biosimilar
• Various diseases • Efficacy (disease worsening during follow-up): 26% (continue therapy) vs 30% (switch) • TEAEs: 70% vs 68% • Immunogenicity: similar ADA levels	• RA • Efficacy: similar levels of ACR20 • TEAEs: 43% vs 35% • Immunogenicity: similar ADA levels	• Psoriasis • No negative effects on efficacy (PASI75 after 12 weeks) were observed • TEAEs: 60% vs 57% • Immunogenicity: comparable

a. Jorgensen KK, et al. *Lancet*. 2017;389:2304-2316; b. Cohen SB, et al. *Ann Rheum Dis*. 2018; 77:914-921;
c. Griffiths CEM, et al. *Br J Dermatol*. 2017;176:928-938.

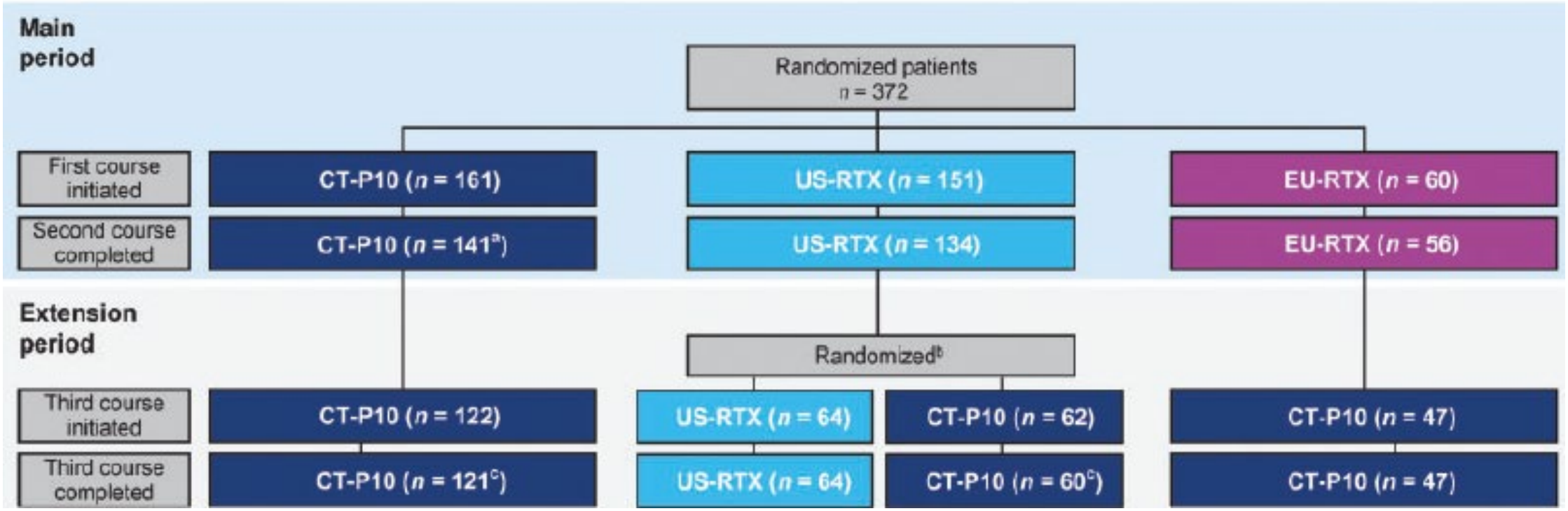
RHEUMATOLOGY

Rheumatology 2019;58:2193–2202
doi:10.1093/rheumatology/kez152
Advance Access publication 10 June 2019

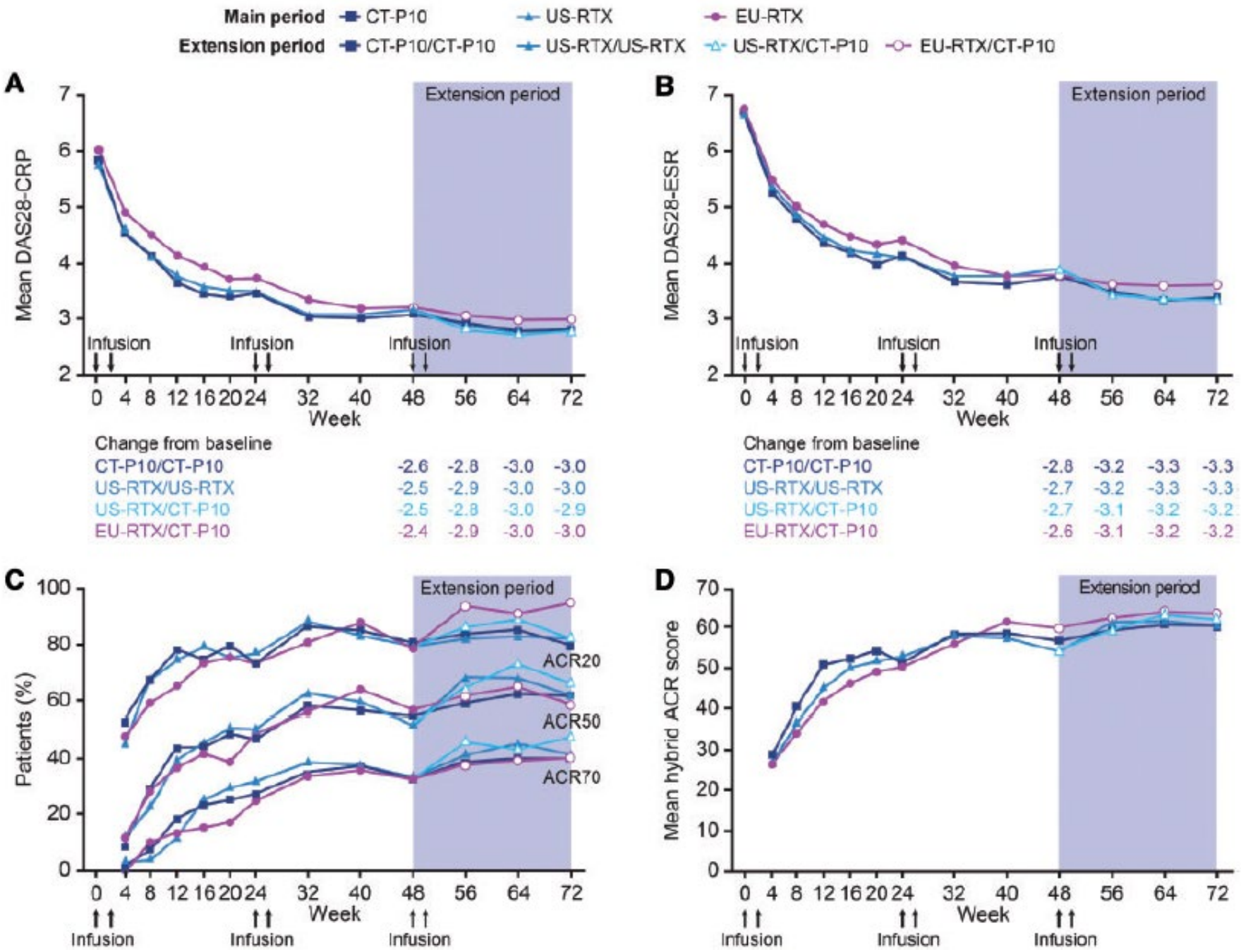
Original article

Efficacy and safety of switching from rituximab to biosimilar CT-P10 in rheumatoid arthritis: 72-week data from a randomized Phase 3 trial

Rituximab και το βιοομοειδές του CT-P10 στη PA



Rituximab και το βιοομοειδές του CT-P10 στη PA



Rheumatology key message

Long-term use of CT-P10 up to 72 weeks was effective and well tolerated in RA

Shim SC, Rheumatology 2019;58:2193-2202

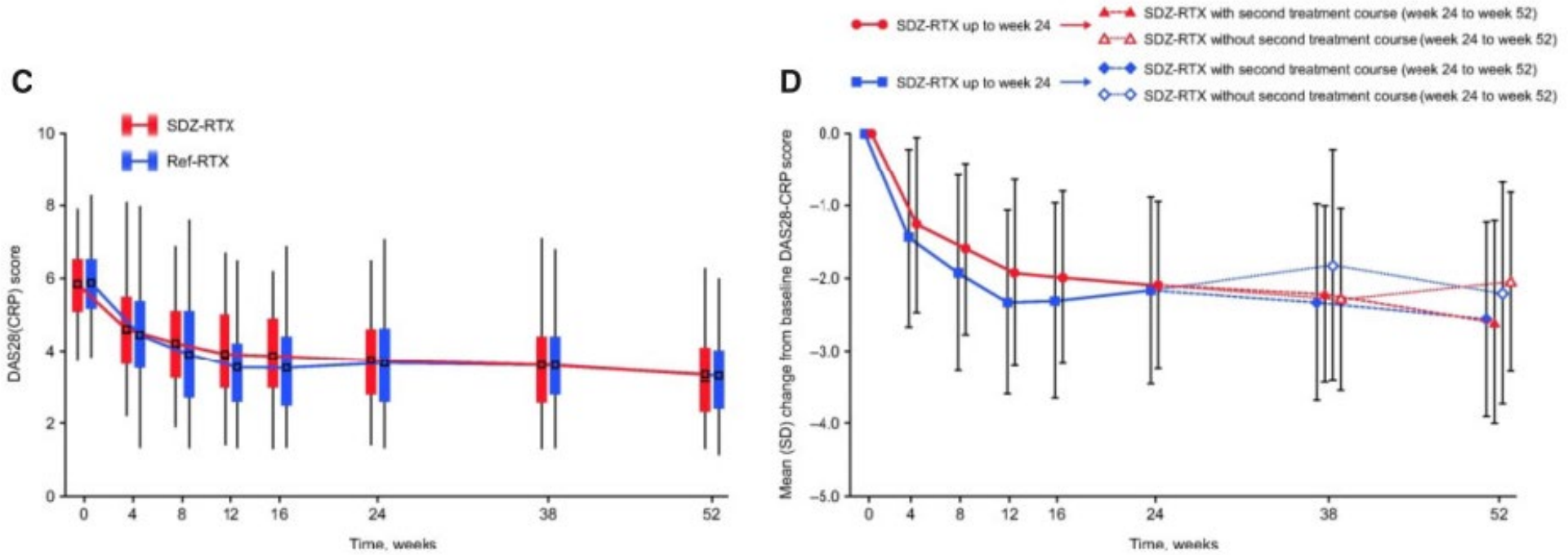
RHEUMATOLOGY

Rheumatology 2020;0:1–7
doi:10.1093/rheumatology/keaa234

Concise report

Rituximab και το βιοομοειδές του από την Sandoz

Efficacy and safety of Sandoz biosimilar rituximab for active rheumatoid arthritis: 52-week results from the randomized controlled ASSIST-RA trial



Rheumatology key messages

- SDZ-RTX demonstrated similar efficacy to reference rituximab (RTX-EU/RTX-US) across multiple measures of rheumatoid arthritis activity.
- SDZ-RTX maintained similar efficacy/safety to RTX-EU/RTX-US in patients receiving one and two treatment courses.
- No differences were observed between treatments in B cell depletion/recovery, and SDZ-RTX immunogenicity was low.

Smolen J, Rheumatology 2020;0:1–7

Μετα-αναλύσεις σε μελέτες αλλαγής από το φάρμακο αναφοράς στο βιοομοειδές

90 studies[a]	58 studies[b]
14 different diseases	**> 12,000 patients**
No difference observed in:	**No difference observed in:**
• Immunogenicity • Safety • Efficacy	• Safety signals • EU pharmacovigilance data

- European expert perspective considers, "switching between comparable versions of the same active substance approved in accordance with the EU legislation is not expected to trigger or enhance immunogenicity"[c]

a. Cohen HP, et al. *Drugs*. 2018;78:463-478; b. Ebbers HC, et al. *Expert Opin Biol Ther*. 2012;12:1473-1485;
c. Kurki P, et al. *BioDrugs*. 2017;31:83-91.

Βιοομοειδή στην κλινική πράξη: Ιατρικά, οικονομικά, και διοικητικά ερωτήματα, καθώς και η θέληση του ασθενούς

- **Υπάρχουν δεδομένα που να δείχνουν διαφορετική κλινική απάντηση ή προφίλ ασφάλειας του βιοομοειδούς έναντι του αρχικού βιολογικού παράγοντα;**
- **Μπορεί να γίνει switching στο βιοομοειδές λόγω έλλειψης αποτελεσματικότητας πρωτοπαθούς, ή δευτεροπαθούς;**
- **Μπορεί να γίνει switching στο βιοομοειδές λόγω κεντρικής διοικητικής απόφασης, κόστους, ή διαθεσιμότητας του φαρμακείου;**
- **Πρέπει να λαμβάνεται υπόψη η επιθυμία του ασθενούς για την πρώτη επιλογή ή αλλαγή της θεραπείας;**

Ζητήματα ανταλλαξιμότητας μεταξύ αρχικού φαρμάκου και βιοομοειδών με ιατρική, και μη ιατρική, σύσταση

MEDITERRANEAN JOURNAL OF RHEUMATOLOGY | 30 2 2019 | SUPPLEMENT I

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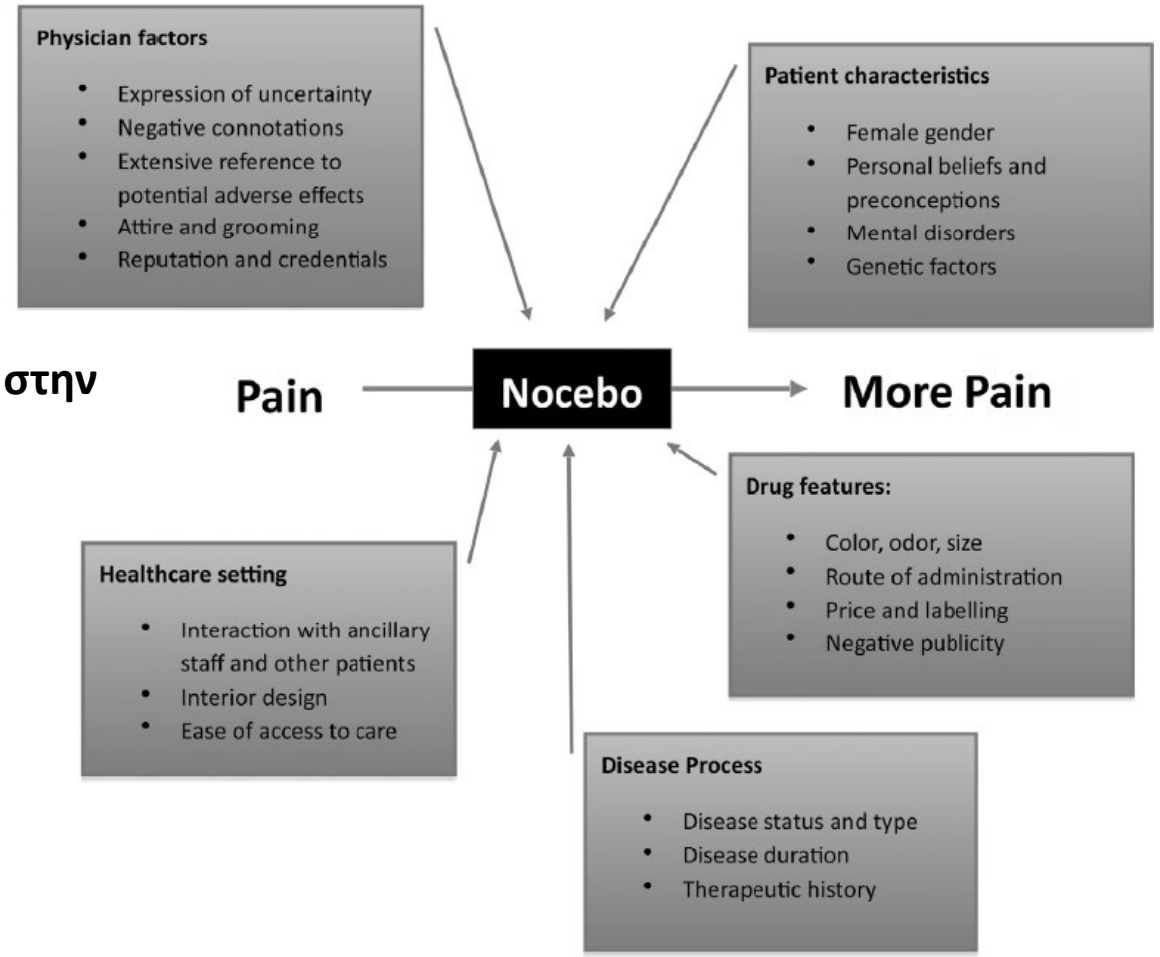
REVIEW

Δράση nocebo και χορήγηση βιοομοειδών

The role of the Nocebo effect in the use of biosimilars in routine rheumatology clinical practice

Evrydiki Kravvariti[1], George D. Kitas[2,3], Petros P. Sfikakis[1]

Παράγοντες nocebo στην κλινική πράξη



Mediterr J Rheumatol 2019;30(Supp 1):63-8

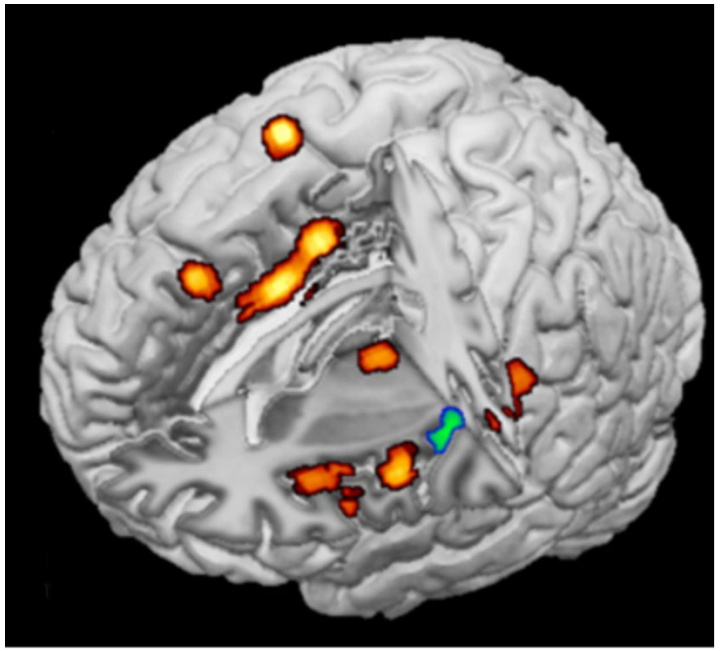
RMD Open
Rheumatic & Musculoskeletal Diseases

REVIEW

Era of biosimilars in rheumatology: reshaping the healthcare environment

Josef S Smolen,[1] Joao Goncalves,[2] Mark Quinn,[3] Fabrizio Benedetti,[4] Jake Yongkwon Lee[5]

Αποδοχή από τον ασθενή της αλλαγής σε βιοομοειδές: δράση nocebo



Neuroimaging of a nocebo responder with activations of brain regions involved in anticipatory anxiety projected onto a 3D rendering model of the brain

When a patient has the expectation that a given treatment will have no benefit, a nocebo effect, which is the opposite of the placebo effect, can occur in clinical trial and routine care settings. If the treatment is given in a negative context, an increase in anticipatory anxiety activates neurochemical systems that increase pain transmission (eg, cholecystokinin and cyclooxygenase), and neuroimaging studies have shown increased activity of brain regions involved in pain processing and emotional regulation (eg, the prefrontal cortex) (figure 5). When a nocebo response, such as perceived side effects or lack of efficacy, occurs in response to active therapy, it can have a negative impact on treatment adherence and outcomes. To avoid contributing to the nocebo effect, it is very important that clinicians carefully consider how they communicate with their patients, and make an effort to frame communications in a positive context

Smolen JS, *RMD Open* 2019;5:e000900

Updating position statement from the European League Against Rheumatism (EULAR) Standing Committee of People with Arthritis/Rheumatism in Europe (PARE) August 2018

- If so-called ‘naïve’ patients (patients who have not taken a biologic so far) should take a biologic, the less expensive biologic (either originator or biosimilar) can be used – as long as there are no contraindications, the patient has been informed and the decision is based on a shared decision between rheumatologist and patient
- No patient should be switched from an original product to a biosimilar against the patient’s decision just to reduce costs-. A switch should always be based on a shared decision between patient and doctor
- As long as no studies exist, a switch between different biosimilars is not recommended
- Original products and biosimilars should not be interchangeable with each other in pharmacies. The exchange of biologics is only considered to be without problems if it is the same product in a different wrapping

Bioidenticals: These are biotechnologically produced medicinal products from a manufacturing process that runs under identical conditions

eular
fighting rheumatic & musculoskeletal diseases together

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Commission

Biosimilars in the EU

Information guide for healthcare professionals

Prepared jointly by the European Medicines Agency and the European Commission

Ευρωπαϊκή Επιτροπή

Τι πρέπει να γνωρίζω για τα βιοομοειδή φάρμακα;

Πληροφορίες για τους ασθενείς

Πληροφοριακό έγγραφο συναίνεσης

Consensus-based recommendations for the use of biosimilars to treat rheumatological diseases

Jonathan Kay,[1] Monika M Schoels,[2] Thomas Dörner,[3] Paul Emery,[4] Tore K Kvien,[5] Josef S Smolen,[2,6] Ferdinand C Breedveld,[7] on behalf of the Task Force on the Use of Biosimilars to Treat Rheumatological Diseases

Οι συστάσεις της EULAR

1.	The availability of biosimilars must significantly lower the cost of treating an individual patient and increase access to optimal therapy for all patients with rheumatic diseases.	100	5	D
2.	Approved biosimilars can be used to treat appropriate patients in the same way as their bio-originators.	100	1b	A
3.	As no clinically significant differences in immunogenicity between biosimilars and their bio-originators have been detected, antidrug antibodies to biosimilars need not be measured in clinical practice.	100	2b	B
4.	Relevant preclinical and phase I data on a biosimilar should be available when phase III data are published.	100	5	D
5.	Since the biosimilar is equivalent to the bio-originator in its physicochemical, functional and pharmacokinetic properties, confirmation of efficacy and safety in a single indication is sufficient for extrapolation to other diseases for which the bio-originator has been approved.	100	5	D
6.	Currently available evidence indicates that a single switch from a bio-originator to one of its biosimilars is safe and effective; there is no scientific rationale to expect that switching among biosimilars of the same bio-originator would result in a different clinical outcome but patient perspectives must be considered.	96	1b	A
7.	Multiple switching between biosimilars and their bio-originators or other biosimilars should be assessed in registries.	100	5	D
8.	No switch to or among biosimilars should be initiated without the prior awareness of the patient and the treating healthcare provider.	91	5	D

Kay J, Ann Rheum Dis 2018;77:165–174

Overview of Biosimilar Use Across Europe

Britain and Norway[a,b]

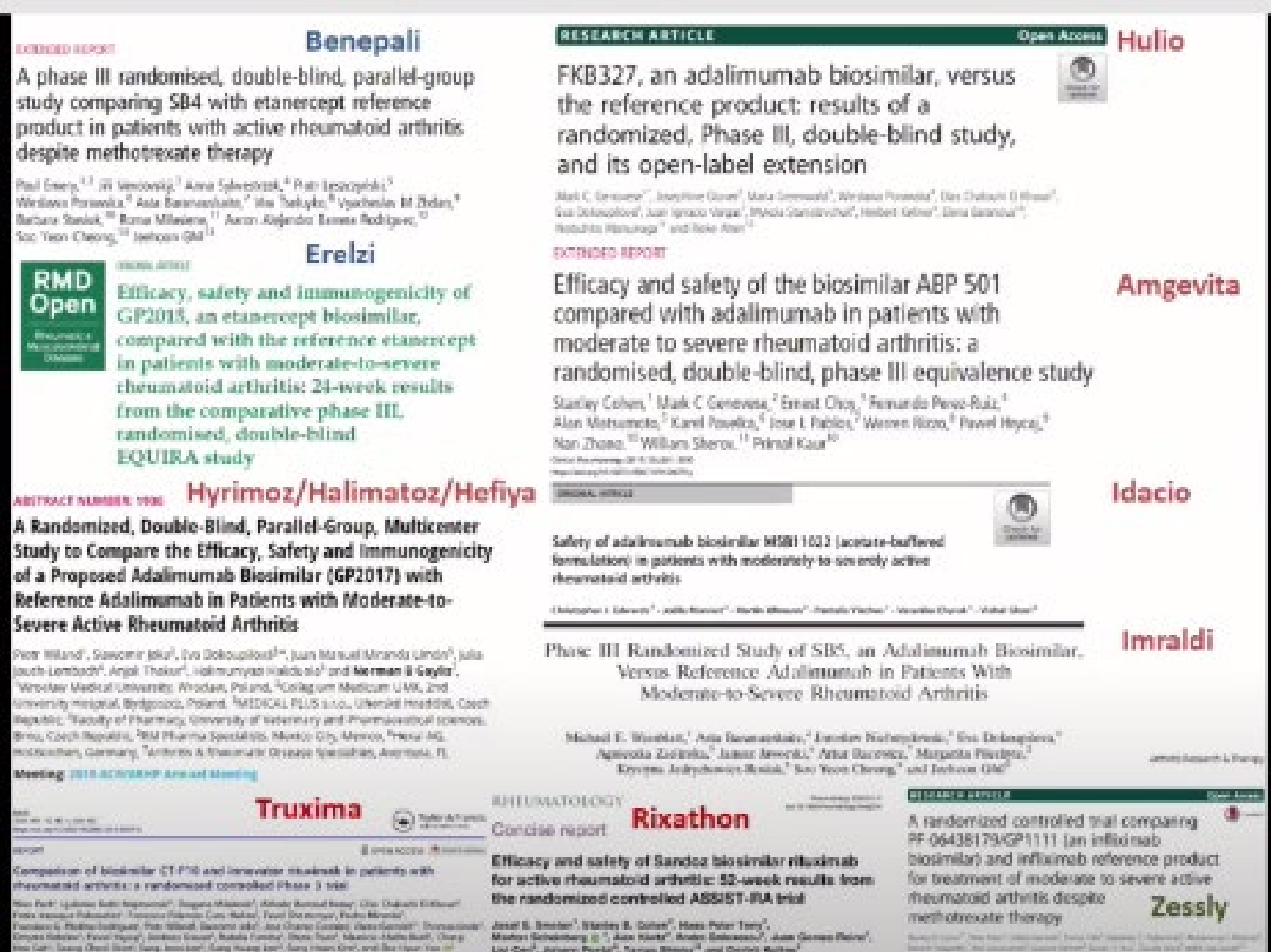
- Up to 90% biosimilar use

Italy[c-e]

- Education route
- Experiencing important increase in biosimilar use

The economic benefits can be gained in every different health system, but it seems to take time and staff skills to generate it, whether it is education- or trial-based

a. NHS England. 2018; b. Biosimilar Development. Norwegian Phenomenon 2018; c. Genazzani A, et al *GaBI J*. 2017 [Epub ahead of print]; d. Biosimilars Law Blog. AIFA 2018; e. Marcianò I, et al. *BioDrugs*. 2016;30:295-306.



Βιοομοειδή: Το μέλλον είναι εδώ

Παπαγόρας Χ, Εαρινές Ημέρες Ρευματολογίας 2020

Βιοομοειδή: Για ποιο λόγο;

NOR-SWITCH Experience

- NOR-SWITCH -- Examined switching from originator infliximab to a biosimilar across several auto-immune diseases (including rheumatic and IBD disorders)
  - Switching from the originator to the biosimilar was not inferior to continued treatment with the originator
  - No differences in safety or immunogenicity were observed
- In Norway, cost savings following biosimilar introduction were 39% in 2014, increasing to 69% in subsequent years

Jørgensen KK, Lancet 2017;389:2304-2316