

Biosimilars in IBD:

Real World Evidence

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Economics

Biologic / Biosimilar Statistics

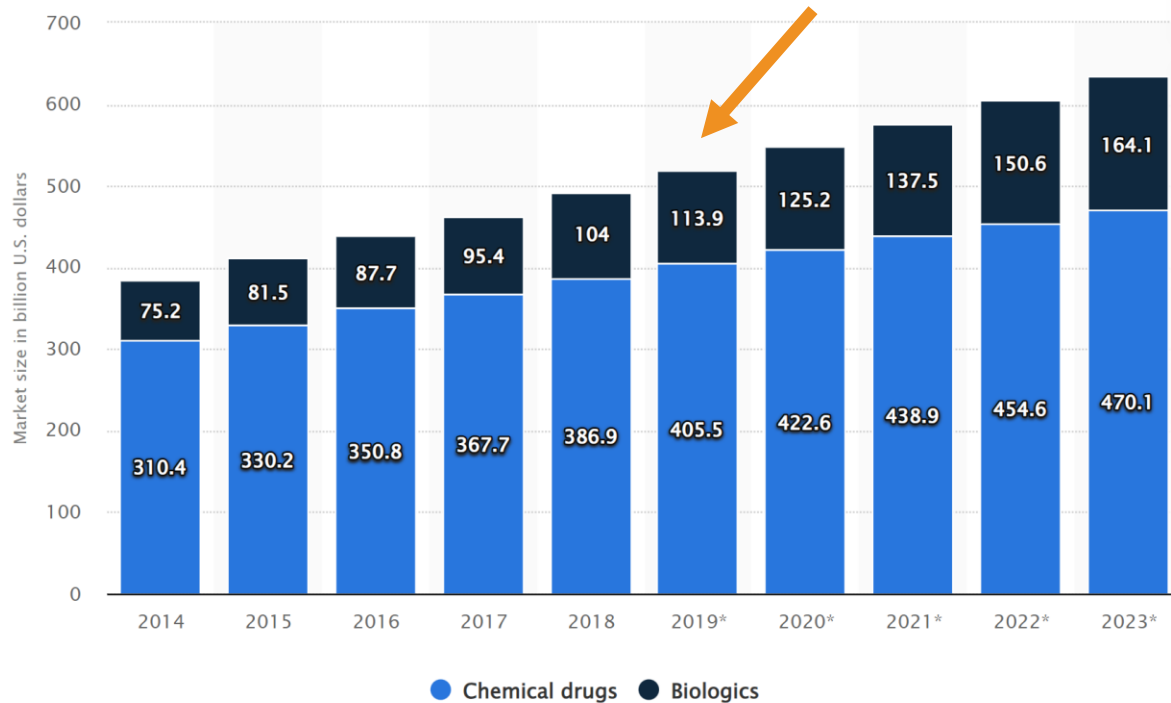
Biologics only account for 2% of all prescriptions written in the US, they are responsible for \$120 billion or 37% of net drug spending in 2017 and, since 2014 to 2019, for 93% of the overall, growth in total spending.

Sources:

<https://www.fdanews.com/ext/resources/files/2020/iqvia-biosimilars-in-us.pdf?1602088219>

Roy A. Biologic medicines: the biggest driver of rising drug prices. Forbes. Published 2019. Updated March 8, 2019. Accessed March 20, 2022.
<https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicinesthe-biggest-driver-of-rising-drug-prices/#3e26982418b0>

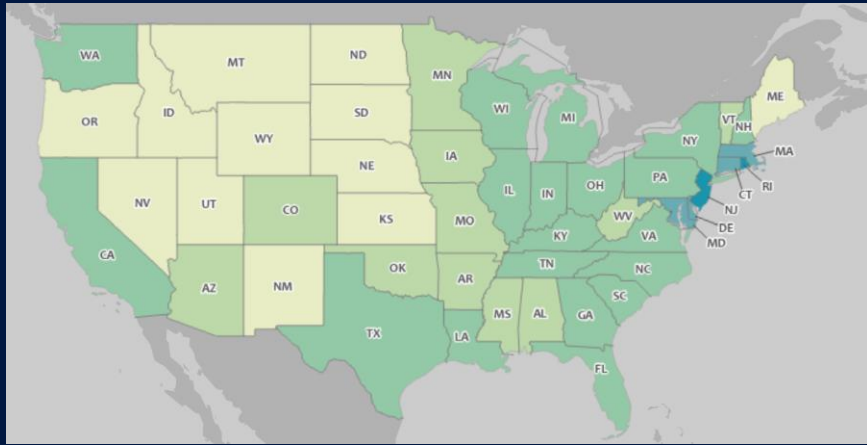
Expenditure: United States Biopharmaceutical Market, Biologic and Chemical Drugs



Reference: <https://www.statista.com/statistics/1085579/pharma-market-size-by-chemical-drug-and-biologics-us/#statisticContainer> (website viewed 03/20/2022)

The US is Single Largest Biopharmaceutical Market, but has Only 4.27% of the World's Population

2019: WORLD POPULATION TOTAL - 7.7 Billion ^{1,2}
2019: US POPULATION TOTAL - 329,064,917 ^{3,4}

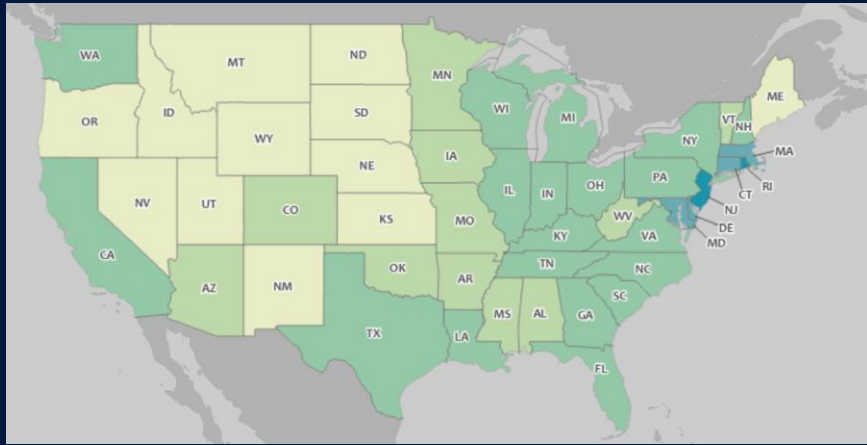


2019:
Global Biologic Market - \$269.1 Billion⁵
US Biologic Market - \$113.9 Billion⁶

1. Population Numbers in Billions: http://www.prb.org/pdf14/2014-world-population-data-sheet_eng.pdf ICH: International Conference on Harmonisation
2. https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf
3. <https://www.census.gov/popclock/>
4. <https://worldpopulationreview.com/countries/united-states-population>
5. <https://www.bccresearch.com/market-research/biotechnology/biologic-therapeutic-drugs-technologies-markets-report.html>
6. <https://www.statista.com/statistics/1085579/pharma-market-size-by-chemical-drug-and-biologics-us/#statisticContainer>

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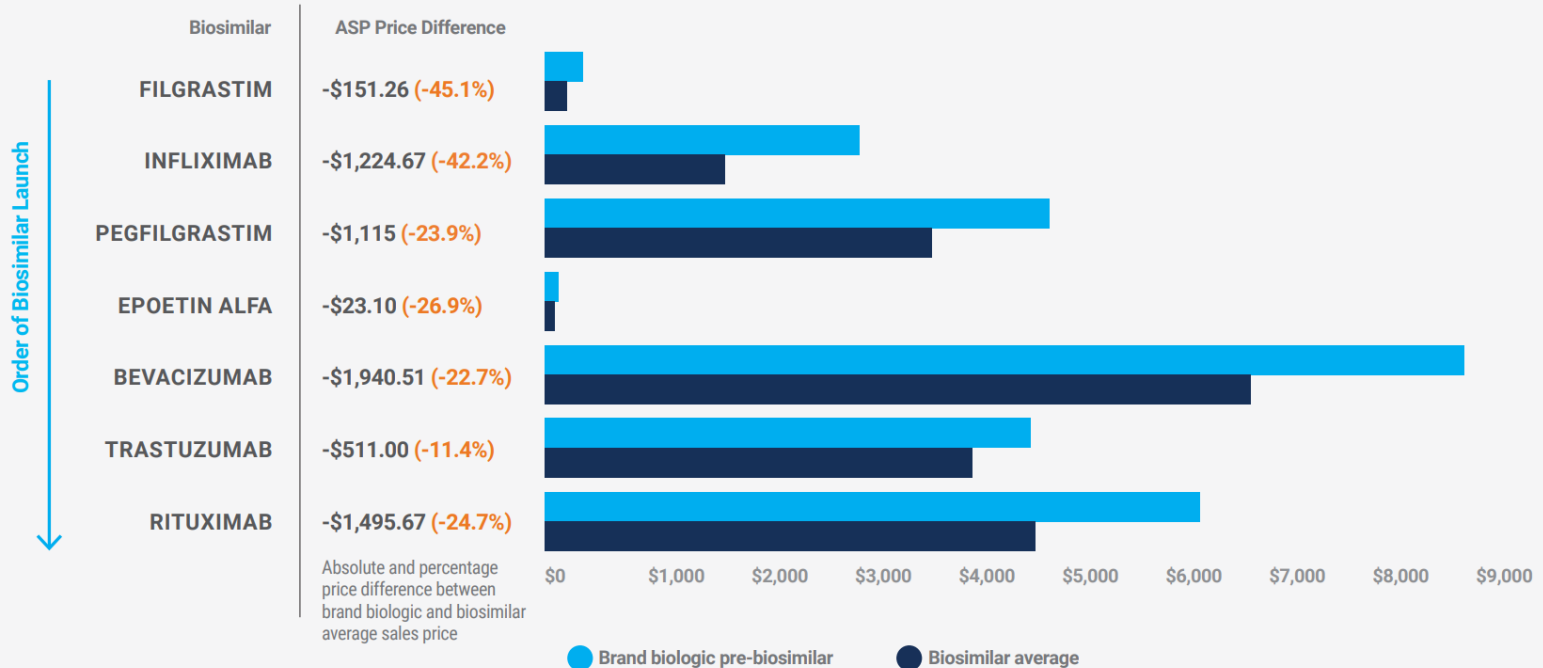
2019:
Global Biologic Market - \$269.1 Billion⁵
US Biologic Market - \$113.9 Billion⁶

In 2019- The US had 42.3% of the Global Biologic Market

1. Population Numbers in Billions: http://www.prb.org/pdf14/2014-world-population-data-sheet_eng.pdf ICH: International Conference on Harmonisation
2. https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf
3. <https://www.census.gov/popclock/>
4. <https://worldpopulationreview.com/countries/united-states-population>
5. <https://www.bccresearch.com/market-research/biotechnology/biologic-therapeutic-drugs-technologies-markets-report.html>
6. <https://www.statista.com/statistics/1085579/pharma-market-size-by-chemical-drug-and-biologics-us/#statisticContainer>

Biosimilars Are Less Expensive Than Their Reference Brand Biologic

ORIGINATOR AND MEAN BIOSIMILAR AVERAGE SALES PRICE, JULY 2020



Source: IQVIA Institute (October 2020) "Biosimilars in the United States 2020-2024; Competition Savings and Sustainability."

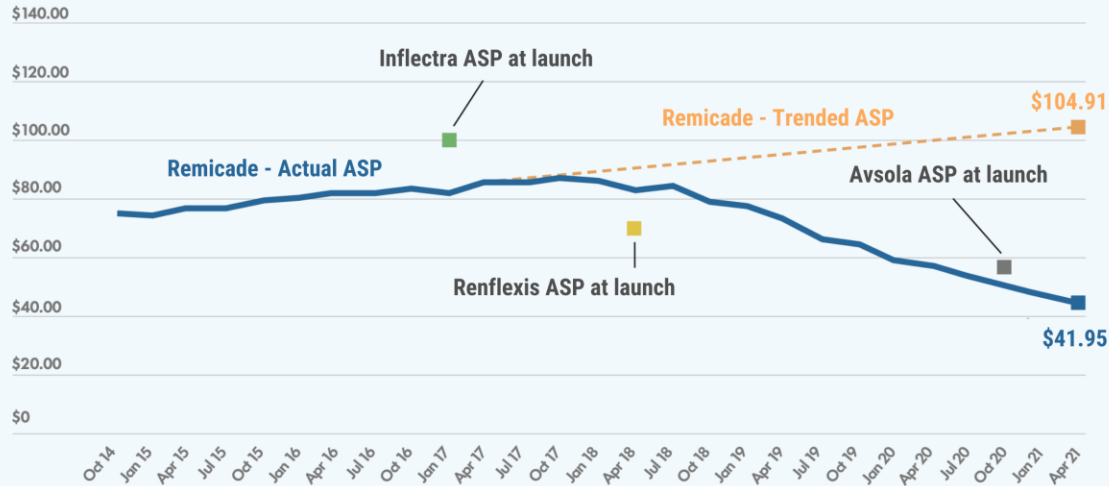
ASP- Average Sales Price

Biologic Agent Cost: Influence of Biosimilar Approval

Infliximab
Dose: 10 mg

Figure 1. Remicade's Actual ASP and Trended ASP Without Biosimilars

Remicade's ASP would have been 150.1% (\$63) higher in April 2021 in the absence of biosimilar competition.



ASP indicates average sales price.

Source: Xcenda, Biosimilars Forum

Reference: <https://www.centerforbiosimilars.com/view/opinion-biosimilars-offer-savings-and-access-for-us-patients>
Accessed 04/03/2022 (with permission)

ASP - Average Sales Price

Are Biosimilars Cost Saving?

- Medicare recorded \$109.6 billion in generic and biosimilar savings in 2020.
- Medicaid saved \$53.8 billion in 2020 through the use of generics and biosimilars

Sources:

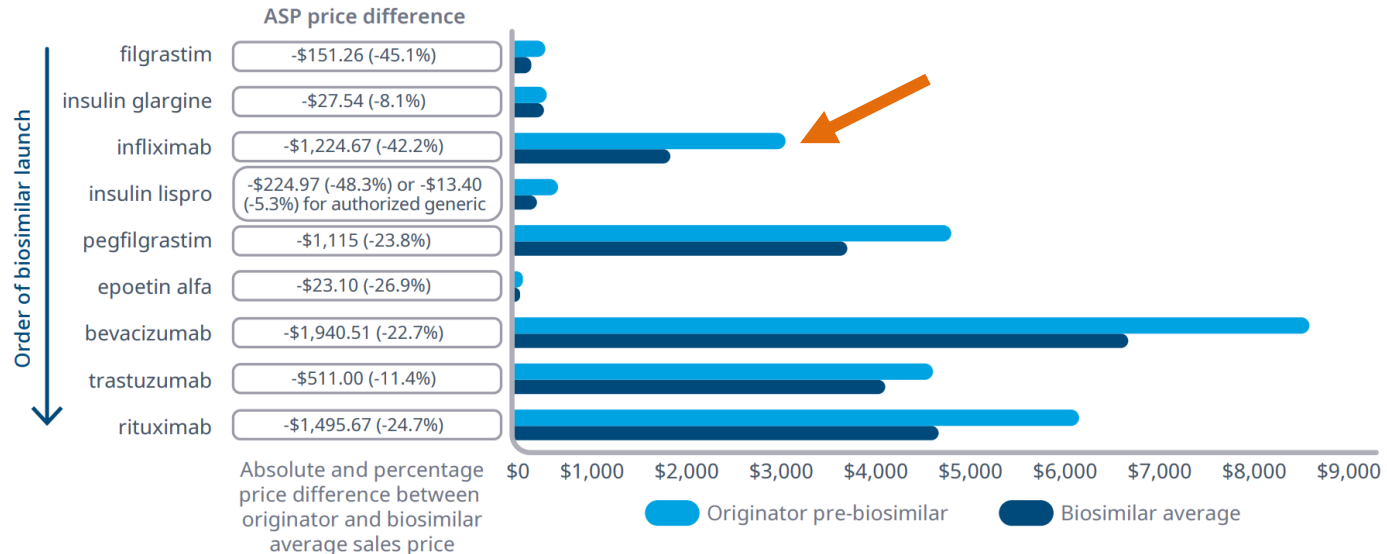
<https://www.fdanews.com/ext/resources/files/2020/iqvia-biosimilars-in-us.pdf?1602088219>

Roy A. Biologic medicines: the biggest driver of rising drug prices. Forbes. Published 2019. Updated March 8, 2019. Accessed March 20, 2022.
<https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicinesthe-biggest-driver-of-rising-drug-prices/#3e26982418b0>

Biosimilars Are Less Expensive Than Their Reference Brand Biologic

Absolute savings from biosimilars vary, with larger savings from more recent launches where originators were more costly

Exhibit 12: Originator and Mean Biosimilar Average Sales Price (ASP) in US\$, July 2020



Source: CMS ASP Jul 2020 accessed Sep 2020; IQVIA National Sales Perspectives, Jul 2020; IQVIA Institute, Sep 2020

ASP- Average Sales Price

ABSTRACT

OBJECTIVES: Biologics account for an increasing share of US prescription drug spending. Biosimilars could lower biologic prices through competition, but barriers to increasing both supply and uptake remain. We projected US biosimilar savings from 2021 to 2025 under different scenarios.

STUDY DESIGN: We projected US spending on biologics over a 5-year period under 3 scenarios: (1) a baseline scenario holding quarter 4 (Q4) of 2020 market conditions constant; (2) under main assumptions allowing for biosimilar market growth and entry; and (3) an upper-bound scenario assuming greater biosimilar uptake, more robust price competition, and quicker biosimilar entry.

METHODS: We first analyzed 2014-2020 US volume and price data from IQVIA's MIDAS database for biologics already facing biosimilar competition to inform model parameter values. We used these inputs to project biosimilar entry, biosimilar volume shares, biosimilar prices, and reference biologic prices. We calculated 2021-2025 new savings from biosimilar competition vs the Q4 2020 baseline.

RESULTS: Estimated biosimilar savings from 2021 to 2025 under our main approach were \$38.4 billion, or 5.9% of projected spending on biologics over the same period. Biologics first facing biosimilar competition from 2021 to 2025 accounted for \$26.1 billion of savings, with \$12.2 billion from evolving market conditions for already-marketed biosimilars. Furthermore, \$24.6 billion of savings under our main approach were from downward pressure on reference biologic prices rather than lower biosimilar prices. Savings were substantially higher (\$124.5 billion) under the upper-bound scenario.

CONCLUSIONS: Biosimilar savings from 2021 to 2025 were \$38.4 billion under our main assumptions. Greater savings may be feasible if managed care and other settings increase biosimilar utilization and promote competition.

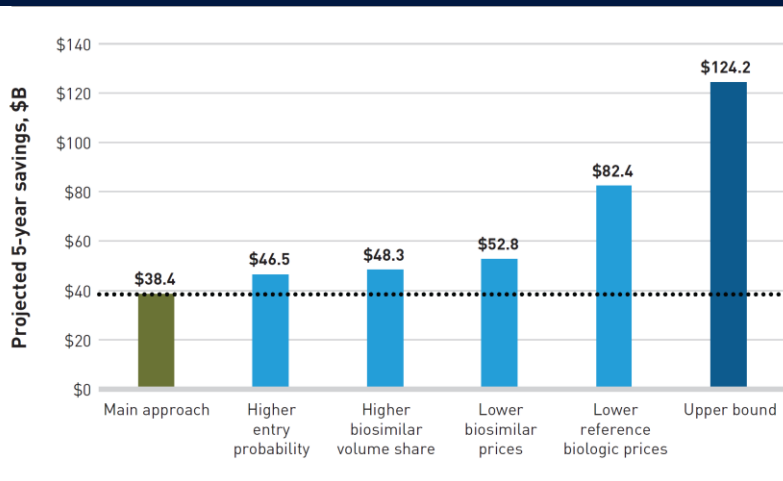
United States Projected Saving on Biologic Agent Use with Use of Biosimilars

Savings projected on 60 biologics from lower biosimilar prices over a 5-year period using 3 scenarios:

- 1.) A baseline scenario holding quarter 4 (Q 4) of 2020 market conditions constant
- 2.) Under main assumptions allowing for biosimilar market growth and entry;
- 3.) an upper-bound scenario assuming greater biosimilar uptake, more robust price competition, and quicker biosimilar entry.

Results:

- Estimated biosimilar savings under the main assumption- \$38.4 Billion (5.9% of projected biologic spending over that time period).

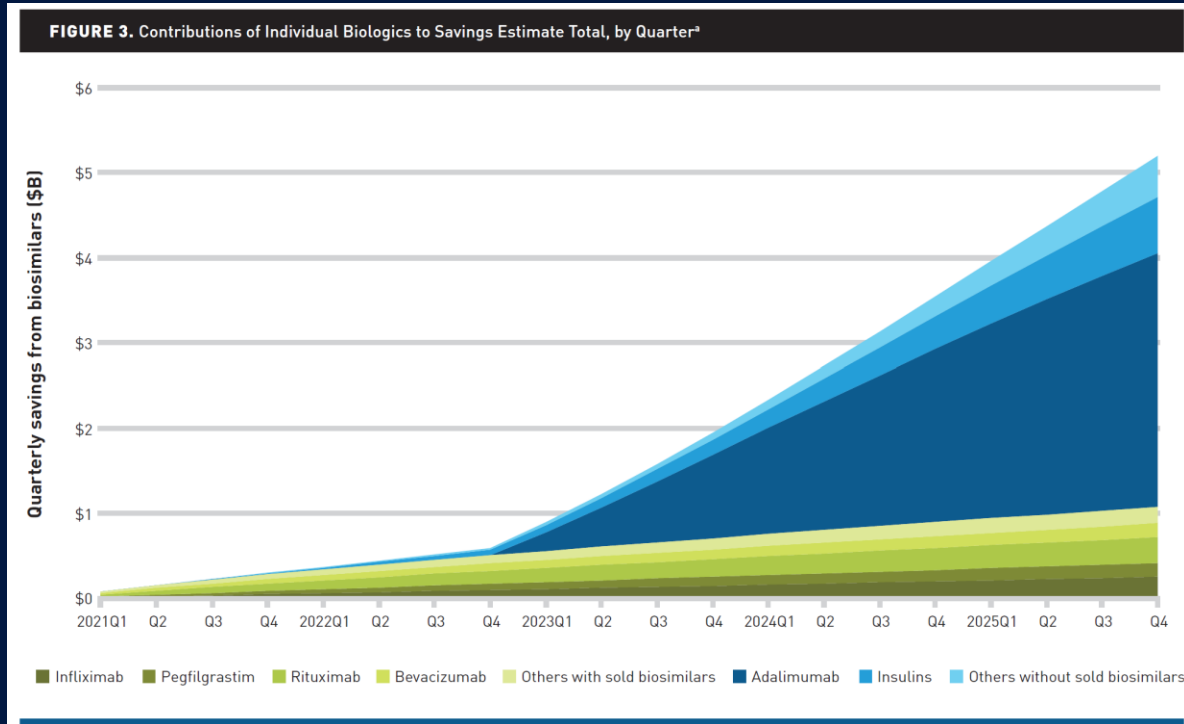


Source: Mulcahy A, et al. Am J Manag Care 2022; 28(7): In Press

<https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025>

Results:

- \$24.6 billion (64.2%) of estimated savings were from downward pressure on reference biologic prices.



Source: Mulcahy A, et al. Am J Manag Care 2022; 28(7): In Press

<https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025>

Evidence for Approved Biosimilars in Management of IBD

Two TNF α Inhibitors FDA-approved for IBD Have Approved Biosimilars

- **Infliximab** (reference): – Adult/Peds (A/P)-CD, A/P-UC
 - Biosimilars – clinical trial data
 - Infliximab-axxq – A/P-CD, A/P-UC (12/2019)
 - Infliximab-qbtx – A/P-CD, AP-UC (12/2017)
 - Infliximab-abda – A/P-CD, A/P-UC (05/2017)
 - Infliximab-dyyb – A/P-CD, A/P-UC (04/2016)

- **Adalimumab** (reference): - A/P-CD, A/P-UC
 - Biosimilars – clinical trial data
 - Adalimumab-adaz – A-CD, A-UC (10/2018)
 - Adalimumab-adbm – A/P-CD, A-UC (8/2017)
 - Adalimumab-atto – A-CD, A-UC (09/2016)
 - Adalimumab-afzb - A-CD, A-UC (12/2019)
 - Adalimumab-bwwd - A-CD, A-UC (07/2019)
 - Adalimumab-fkjp - A-CD, A-UC (12/2020)
 - Adalimumab-aqvh- A/P- CD, A-UC (12/2021)

A- Adults P-Pediatrics UC- Ulcerative Colitis CD- Crohn's Disease

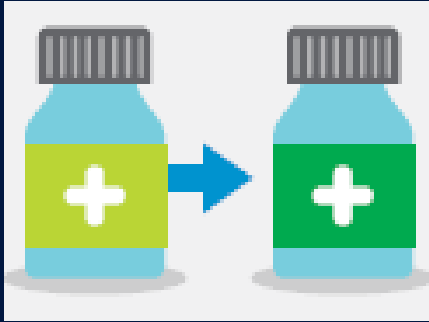
Sources: <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information> and <https://purplebooksearch.fda.gov>

Possible Clinical Scenarios for Biosimilars Use in IBD



- Prescriber choice of reference product or biosimilar
- Prescriber elects to switch to another biologic
- Prescriber elects to maintain original biologic
- Prescriber elects to switch to biosimilar (Non-medical SWITCH)
- If attributed to high titer of ADA, switch to biosimilar is not supported
- Prescriber elects to switch to another therapy

Switching to a Biosimilar Should Be a Clinical Decision



- **Switching** is the decision of the health care provider to change a patient from one drug to another drug with the same therapeutic **intent**
- **Substitution**: the practice of authorizing pharmacists to substitute one drug for another without the prescribing physician's prior consent
- **Interchangeability**: FDA terminology referring to multiple switching back and forth between the reference product and a biosimilar

The decision to switch a patient from an originator medicine to a biosimilar should always be a clinical decision made by a treating health care provider on an individual patient basis, supported by scientific evidence and with patient awareness.

CT-P13 Clinical Trials Supporting the Therapeutic Indications

Disease	Clinical Trial	Population	N	Primary Endpoint	Dosing Regimen
Rheumatoid Arthritis	PLANETRA (phase III)	Established RA	606	ACR20 at Wk 30	CT-P13 or Remicade (3 mg/kg) at Wks 0, 2, 6 followed by q8w infusions through Wk 54 LTE: Only CT-P13 from Wk 54-102 (Remicade pts switch to CT-P13 at Wk 54)
Ankylosing Spondylitis	PLANETAS (phase I)	Active AS	250	PK equivalence at steady state (AUC C _{max,ss})	CT-P13 or Remicade (5 mg/kg) at Wks 0, 2, 6 followed by q8w infusions through Wk 54 LTE: Only CT-P13 from Wk 54-102 (Remicade pts switch to CT-P13 at Wk 54)

Yoo et al. *Ann Rheum Dis.* 2013;72:1613-20.

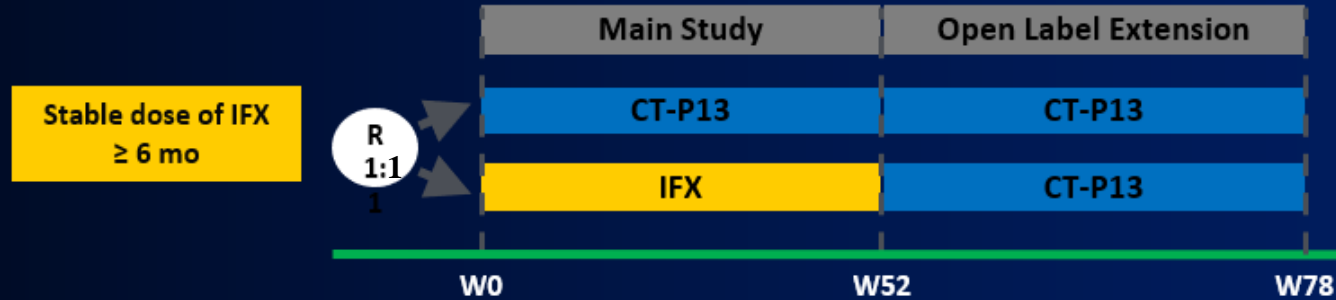
Park et al. *Ann Rheum Dis.* 2013;72:1605-1612.

Yoo et al. ACR 2013. Abstract #L1.

Parkm et al. ACR 2013. Abstract #L15.

www.clinicaltrials.gov accessed 20 March 2022 (<http://www.clinicaltrials.gov/ct2/show/NCT02096861?term=CT-P13&rank=1>).

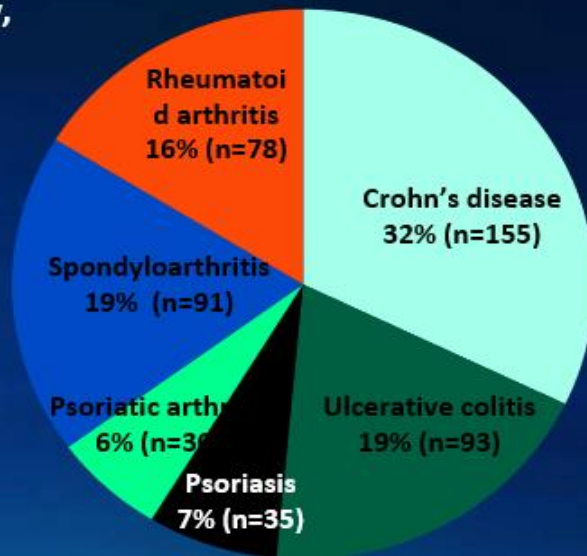
Nor-Switch: Study Design



- Double-blind, non-inferiority study (15% margin)
- Primary endpoint: Occurrence of disease worsening 52wks
- Assumption: 30% disease worsening in IFX arm

Nor-Switch: Disease Indication

Multicenter study,
40 sites across
Norway

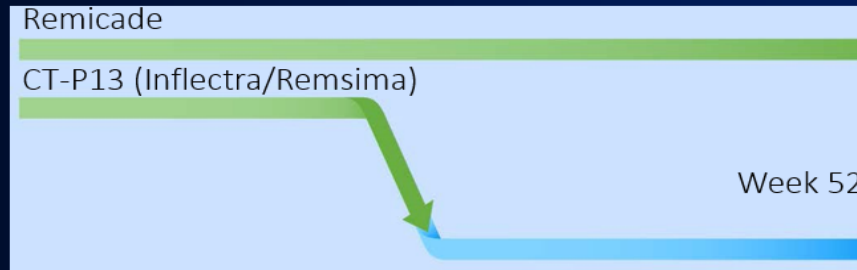


N=482

Nor-Switch Trial

Phase IV multi-indication prospective non-medical switch study in Norway by Norwegian govt.

52 weeks randomized, double-blind non-inferiority study



RESULTS:

Primary outcome: disease worsening at 12 months

Remicade 53/202 (26.2%)

CT-P13 61/206 (29.6%)

Anti-drug antibodies:

Remicade 7.1%

CT-P13 7.9%

Disease Worsening

	Remicade	CT-P13
CD (n=155)	14 (21.%)	23 (36.5%)
UC (n=93)	3 (9.1%)	5 (11.9%)

Phase 3: Non-Medical Switch: Active Crohn's Disease RCT

- Sites
 - 58 centers
 - United States, 11 European countries, Israel, Korea, Brazil, Mexico
- Inclusion:
 - Moderate-severe active bio-naïve CD
 - 220 patients, 54 weeks
 - Randomized 1:1 to IFX / CT-P13 to week 30
 - Randomized 1:1:1:1 to one of four maintenance strategies to week 54
 - IFX–IFX,
 - IFX–CT-P13,
 - CT-P13–IFX,
 - CT-P13–CT-P13

Phase 3: Non-Medical Switch: Active Crohn's Disease RCT

	CT-P13 (n=111)	Infliximab (n=109)	Difference
Week 6			
CDAI-70	77 (69.4%; 95% CI 59.9 to 77.8)	81 (74.3%; 95% CI 65.1 to 82.2)	-4.9% (-16.9 to 7.3)
CDAI-100	67 (60.4%; 50.6 to 69.5)	70 (64.2%; 54.5 to 73.2)	-3.9% (-16.7 to 9.6)
Clinical remission	47 (42.3%; 33.0 to 52.1)	49 (45.0%; 35.4 to 54.8)	-2.6% (-16.2 to 10.6)
Week 14			
CDAI-70	96 (86.5%; 78.7 to 92.2)	96 (88.1%; 80.5 to 93.5)	-1.6% (-10.7 to 7.7)
CDAI-100	78 (70.3%; 60.9 to 78.6)	83 (76.1%; 67.0 to 83.8)	-5.9% (-17.7 to 6.3)
Clinical remission	59 (53.2%; 43.4 to 62.7)	60 (55.0%; 45.2 to 64.6)	-1.9% (-15.2 to 11.8)
Week 30			
CDAI-70	85 (76.6%; 67.6 to 84.1)	82 (75.2%; 66.0 to 83.0)	1.3% (-10.3 to 12.9)
CDAI-100	80 (72.1%; 62.8 to 80.2)	80 (73.4%; 64.1 to 81.4)	-1.3% (-13.3 to 10.6)
Clinical remission	61 (55.0%; 45.2 to 64.4)	62 (56.9%; 47.0 to 66.3)	-1.9% (-15.2 to 11.7)

Data are n (%; 95% CI). CDAI=Crohn's Disease Activity Index.

Table 2: CDAI-70 response, CDAI-100 response, and clinical remission at weeks 6, 14, and 30

Conclusion:

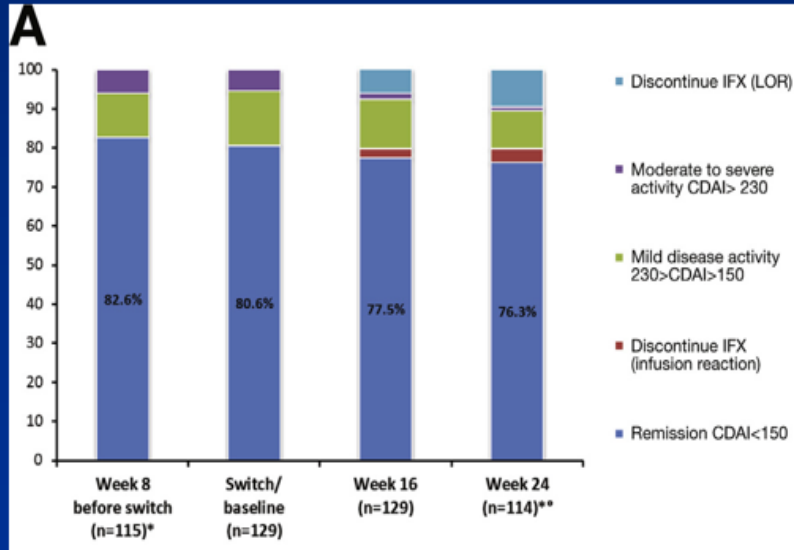
This study showed non-inferiority of CT-P13 to infliximab originator in patients with active Crohn's disease.

Non-Medical Switch: IBD Hungary

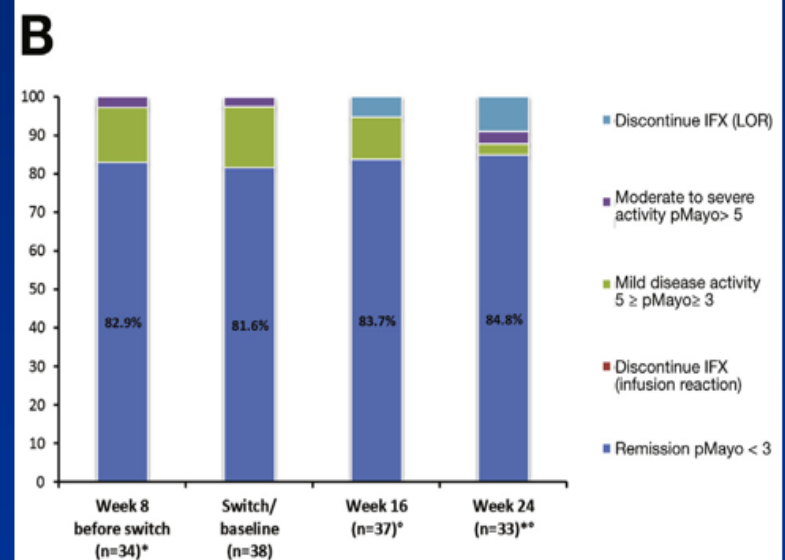
- Prospective observational cohort
- 4 centers in Hungary
- 174 patients (136 CD, 38 UC), 24 weeks
- Patients in remission on CT-P13
- All switched from CT-P13 to originator IFX
- Clinical remission similar (~80%) 8 week before switch, switch, week 16, week 24 (p = 0.60 for CD, 0.98 for UC)
- Antibodies: switch vs. week 16: 16.2% vs. 16.9%

Non-Medical Switch : IBD Hungary

NMS switch from biosimilar to originator IFX in CD
Disease activity



NMS switch from biosimilar to originator IFX in UC
Disease activity



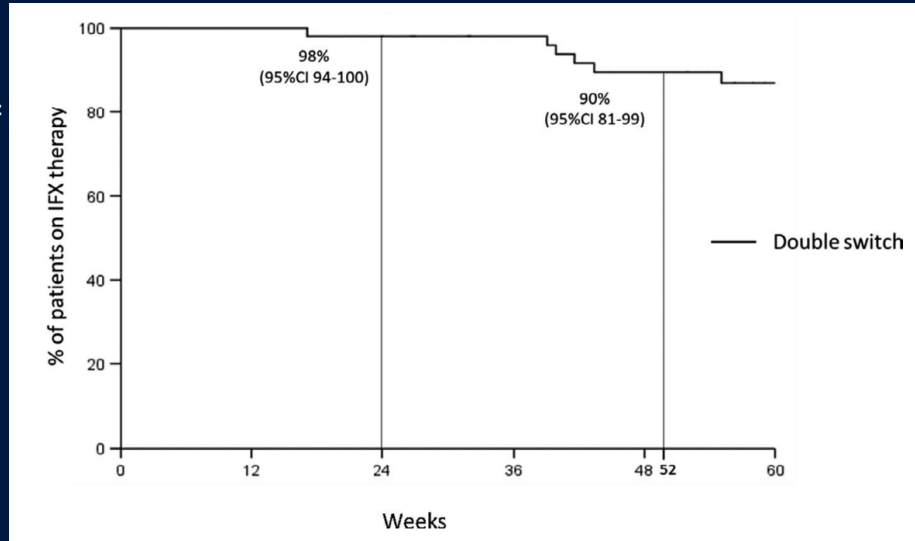
Medical Switching to Biosimilar Definition

- Medical Switching - the switching of a patient's medicine, for the patient's health and safety.
- No studies in patients with IBD to date for 'medical switching'
- Clinical scenarios for medical switching-
 - Primary non-response
 - Loss of response
 - Adverse effects

Double Switched Patients: Continuing Therapy and AEs

Study evaluated the safety and efficacy of switching from originator IFX to CT-P13 and subsequently to SB2 (double switch) in patients with IBD.

Overall proportion of double-switched patients continuing infliximab therapy over time.



CI, confidence interval;
IFX, infliximab

TABLE 2 Overall frequency of adverse events in the double switch or single switch groups

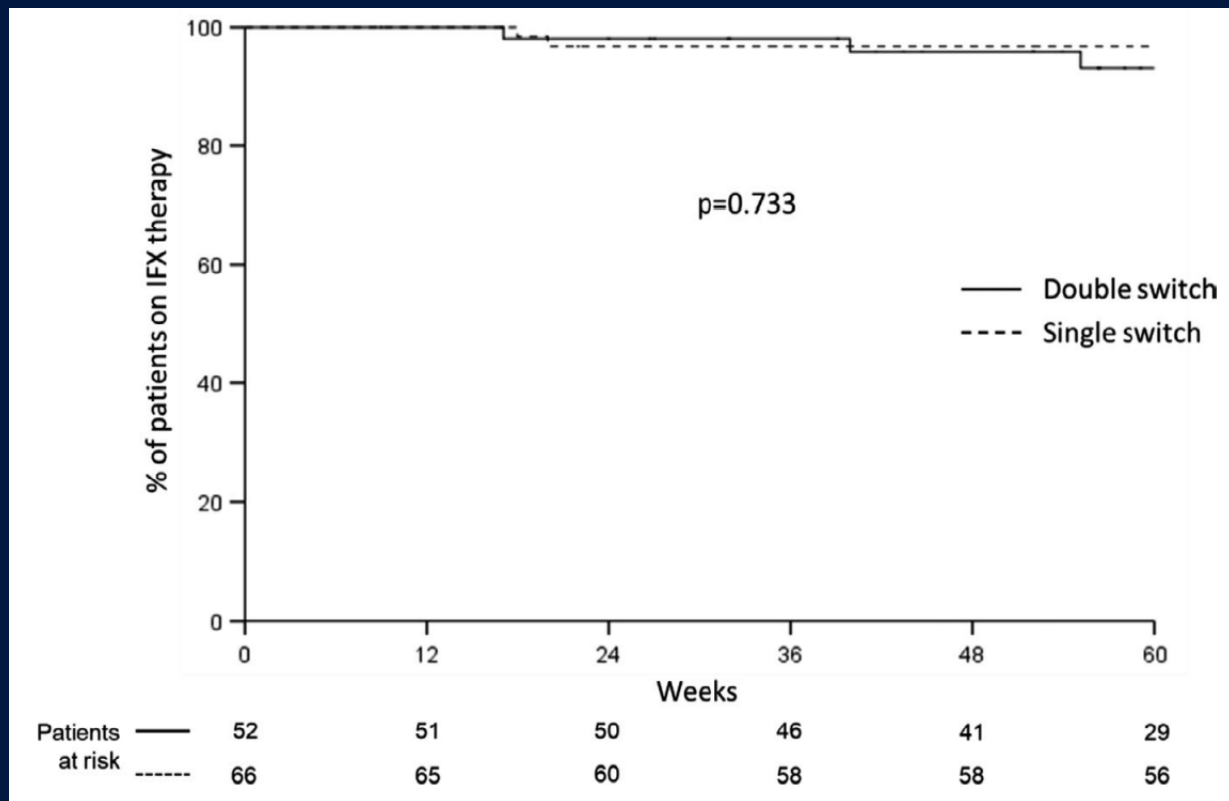
	Double switch n = 52	Single switch n = 66	p value ^a
Total AE, n (%)	5 (9.6)	8 (12.4)	0.772
Infusion reactions, n (%)	0	5 (7.2)	0.066
Cutaneous, n (%)	2 (3.8)	1 (1)	0.582
Infectious, n (%)	2 (3.8)	0	0.192
Articular, n (%)	1 (1.9)	1 (0.5)	1.000
Neurological, n (%)	0	1 (0.5)	1.000
Immuno-mediated, n (%)	1 (1.9)	1 (0.5)	1.000
Neoplastic, n (%)	0	0	NA
Other, n (%)	0	1 (0.5)	1.000
Total SAEs (CTCAE 4–5), n (%)	0	0	NA
Stop for AEs, n (%)	2 (3.8)	4 (6.1)	0.693

Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; NA, not applicable; SAE: serious adverse event.

^aChi-square or Fisher's exact test.

Double Switched Patients: Continuing Therapy and AEs

Proportion of patients discontinued from infliximab because of adverse events over time, according to a double-/single-switch strategy.

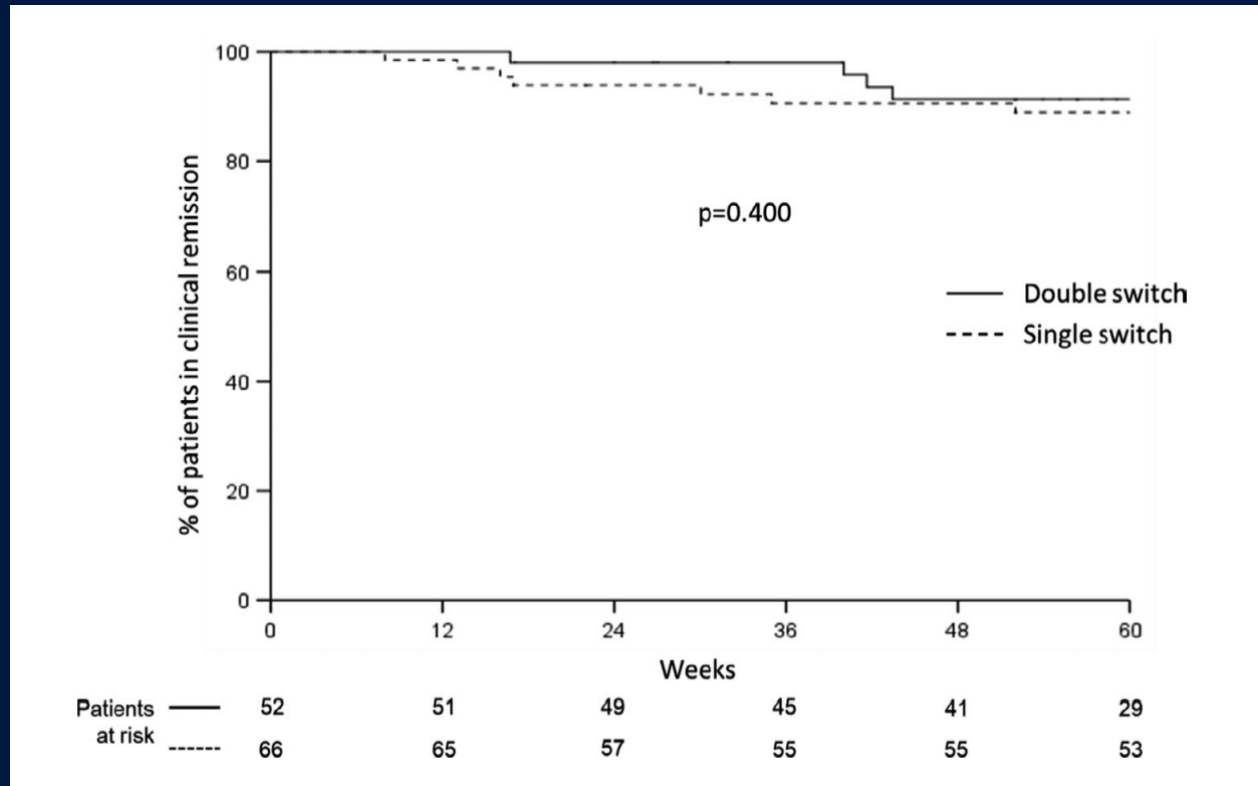


IFX, infliximab

Mazza S et al. *Clin Transl Sci.* 2022;15:172–181.

Double Switched Patients: Continuing Therapy and AEs

Proportion of patients maintaining the clinical response (included optimized cases) over time, according to a double-/single-switch strategy



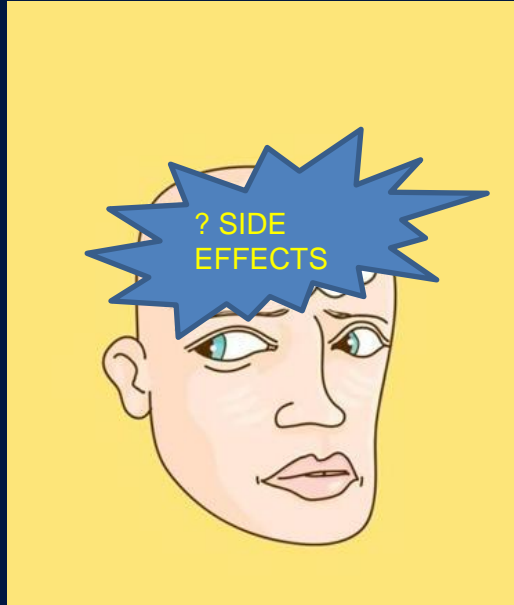
Meta-Analysis: Discontinuation Rates Following a Switch From a Reference to a Biosimilar Biologic in Patients with IBD

- A total of 30 observational studies were included, involving 3,594 patients with IBD
- The discontinuation rates increased over time, and were
 - 8 % at 6 months,
 - 14 % at 12 months, and
 - 21 % at 24 months.
- The main reasons for drug discontinuation and their respective risks were:
 - disease worsening - 2%
 - remission - 4%
 - loss of adherence - 4%
 - adverse events - 5%
 - loss of response - 7%

The quality of the evidence ranged from low to very low depending on the outcome analyzed.

- Subjective symptoms leading to drug discontinuation were infrequently reported, and the nocebo effect was clearly assessed in just one of the included papers.

Nocebo: Definition



Nocebo response:

Defined as an unexplained, unfavorable therapeutic effect subsequent to a non-medical switch from originator biologic to biosimilar biologic with regaining of the beneficial effects after reinitiating the originator

Avoiding the Nocebo Effect When Switching

Nocebo Effect

- Poor clinical outcomes or AE's caused by negative expectations of a drug or reluctance to switch treatment ^{a, b}
 - Can occur with placebo drugs^b
 - Not a direct result of specific pharmacologic action of a drug^c

Prevention Strategy^{b,c}

- Screening and education can mitigate potential nocebo effects and ensure patient comfort with the switch in therapy

- a.) Kristensen LE, et al BioDrugs. 2018; 32: 397-404
b.) Colloca L, et al. JAMA 2012; 307; 567-568.
c.) Barsky AJ, et al. JAMA 2002; 287: 622-627.

Nocebo Response in IBD

146 patients invited to participate; 125 elected to participate

- IBD – 101 patients
 - UC- 28 patients
 - CD – 73 patients
- Rheumatoid Arthritis- 9 patients
- Psoriatic Arthritis- 10 patients
- Ankylosing Spondylitis- 5 patients

- All agree to transition to biosimilar IFX
 - Mean duration of treatment: 2.9-4.6 years
 - 86% and 79% of patients with CD and UC remained on biosimilar after median of 4 infusions
 - Seven patients with IBD developed symptoms and biologic evidence of loss of response
 - 5/7 developed neutralizing antibodies

Nocebo Response in IBD

- Nocebo: 16/125 (12.8%) were designated as nocebo response patients
 - Feeling of less exerted or diminished effect
 - Chills during infusion
 - Numbness of facial skin with tingling limbs
 - New onset headache
- No significant longitudinal change in disease activity assessments, PK or laboratory outcomes

Biosimilars in IBD: Concerns

- Uncertain safety (few trials) with double and triple switches
- Currently, there is no published data on mucosal healing efficacy
- ? Need to use concomitant immunomodulators when doing a triple switch ?
- Other issues- education inadequate....

Barriers to Adopting Biosimilars: Survey of Managed Care and Specialty Pharmacy Professionals

Design

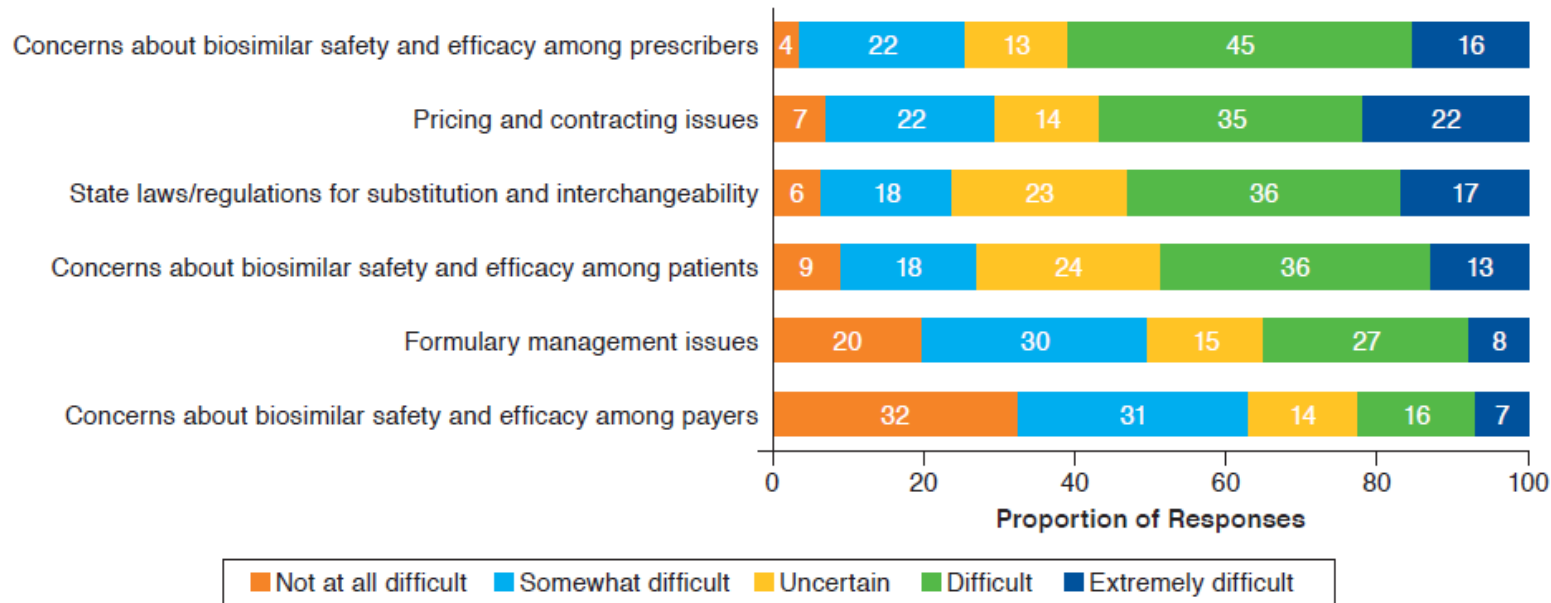
- Invitations to complete an online survey were emailed by the Academy of Managed Care Pharmacy (AMCP) to members and customers and to contacts sourced from a commercial database
- In addition to questions on respondent demographics and perceptions of biosimilars, the survey listed 16 strategies for overcoming key barriers to biosimilar adoption.
- On a 5-point scale, participants rated their opinion on the likelihood that each strategy would have the potential to assist in achieving BPCIA goals.

Results

- A total of 300 managed care and specialty pharmacy professionals completed the survey.

Barriers to Adopting Biosimilars: Survey of Managed Care and Specialty Pharmacy Professionals

FIGURE 2 Ratings of Difficulty in Overcoming Designated Barriers to Biosimilar Adoption



Note: The barriers are ordered by the highest to lowest percentages of pooled ratings of difficult and extremely difficult.

IBD Patients' Perspectives on Biosimilars

Methods:

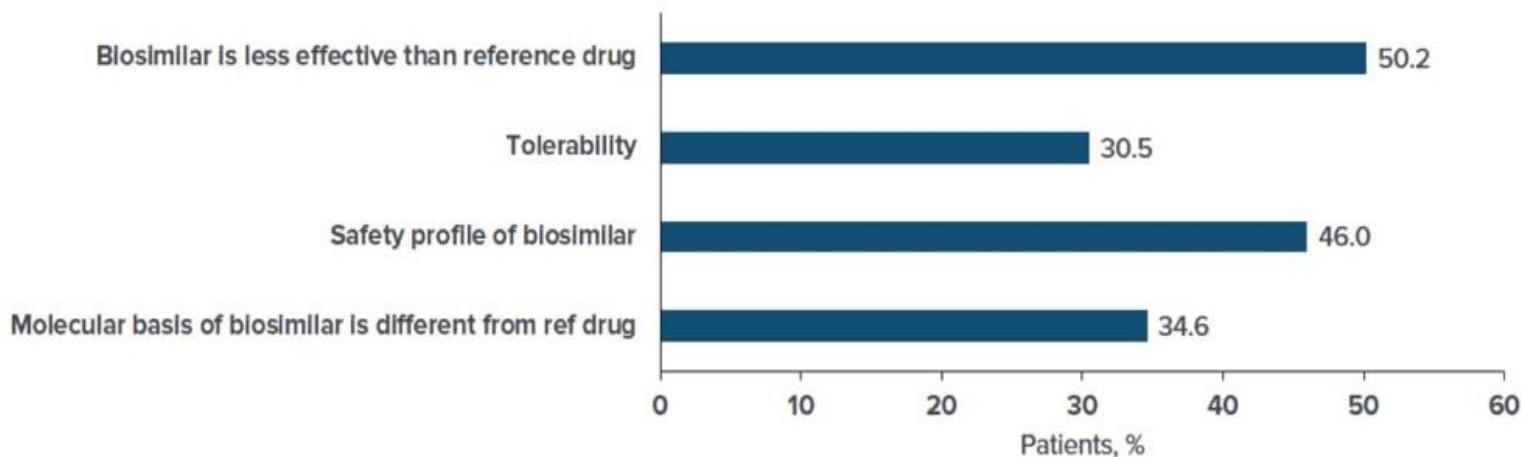
- An online survey consisting of 19 questions was made available by the European Federation of Crohn's and Ulcerative Colitis Associations between July 2018 and December 2018.
- Only respondents who had heard of biosimilars were asked to respond to all of the questions.

Results:

- In total, 1619 patients with inflammatory bowel disease responded the questionnaire.
- Most respondents were from Europe (79%), followed by Asia (8%), South America (7%) and Africa (5%).

IBD Patients' Perspectives on Biosimilars

- 44% of patients (N = 1355) in the survey had heard of biosimilars
- Patients expressed the following concerns:



Shared Decision Making: Definition

- Shared decision making occurs when a health care provider and a patient work together to make a health care decision that is best for the patient
- The optimal decision takes into account evidence-based information about available options, provider's knowledge and experience, patient's values and preferences

What is the SHARE Approach?

- **The SHARE Approach is a five-step process for shared decision making that includes exploring and comparing the benefits, harms, and risks of each health care option through meaningful dialogue about what matters most to the patient**

The **SHARE** Approach

Essential Steps of Shared Decision Making

Five steps for you and your patients to work together to make the best possible health care decisions.

Step 1:

Seek your patient's participation

Communicate that a choice exists and invite your patient to be involved in decisions.

Step 2:

Help your patient explore and compare treatment options

Discuss the benefits and harms of each option.

Step 3:

Assess your patient's values and preferences

Take into account what matters most to your patient.

Step 4:

Reach a decision with your patient

Decide together on the best option and arrange for a followup appointment.

Step 5:

Evaluate your patient's decision

Plan to revisit decision and monitor its implementation.



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Effective Health Care Program

www.ahrq.gov/shareddecisionmaking

April 2014 AHRQ Pub. No. 14-0026-2-EF

Reference:

[ahrqhttps://www.ahrq.gov/health-literacy/professional-training/shared-decision/index.html.gov](https://www.ahrq.gov/health-literacy/professional-training/shared-decision/index.html.gov)

Biosimilars in IBD: Concerns

- Uncertain safety (few trials) with double and triple switches in patients with IBD
- Currently, there is no published data on mucosal healing efficacy- in IBD patients
- ? Need to use concomitant Immunomodulators when triple switch ?
- Education initiatives are critical