Assimilating & Assessing Biosimilars in Real-World Clinical Settings

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DISCLOSURE

Catherine Pham and Rita Hui have no potential conflicts of interest to disclose.

LEARNING OBJECTIVES

- Identify barriers to adoption of biosimilars in the U.S.
- Discuss approaches to facilitating health system acceptance and adoption of biosimilars.
- Describe real-world outcomes research methodology for evaluating effectiveness and safety of biosimilars.
- Review examples of real-world research studies evaluating biosimilars.

A patient's insurance plan prefers them to use a biosimilar instead of the prescribed reference biologic (e.g. filgrastim-sndz/Zarxio® vs. filgrastim/Neupogen®). Neither the prescriber nor the patient are familiar with biosimilars – how do you feel about answering their questions and dispensing the preferred product?

a) Very confident

b) Somewhat confident

c) Not confident

The patient has been stable on the reference biologic product for several months, so both prescriber and patient express concerns about switching. How do you feel about answering their questions and dispensing the preferred biosimilar product now?

a) Very confident

b) Somewhat confident

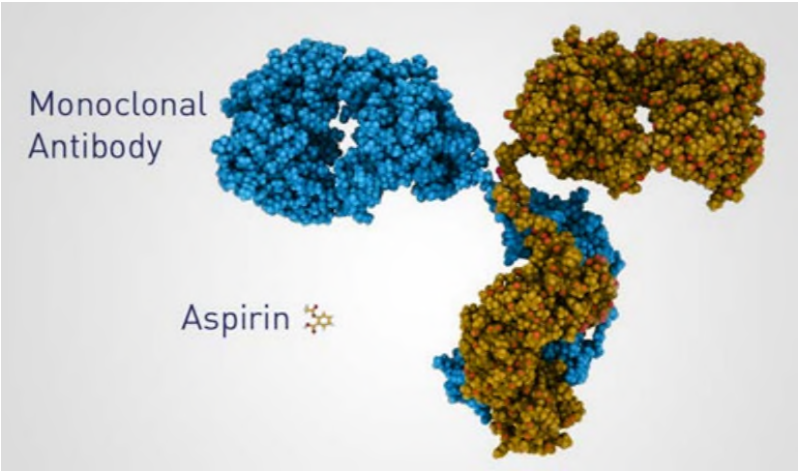
c) Not confident

BACKGROUND

What are biosimilars?

BIOSIMILARS ARE BIOLOGICS

- Produced in living system (ex: bacteria, animal, human)
- Large, complex molecules
  - Can consist of proteins, nucleic acids, and/or living cells
- Biosimilar products are highly similar to an existing FDA-approved reference biologic product



(1) FDA. Biological product definitions, 2019.

	BIOLOGIC/BIOSIMILAR	BRAND/GENERIC
Structure	Large molecule, complex, unstable	Small molecule, well-defined, stable
Manufacturing	Living cell culture, impossible to ensure identical copy	Chemical synthesis, able to create identical copy
Immunogenicity	Likely	Not likely
Approval process	(Abbreviated) biologic license application	(Abbreviated) new drug application
Regulation	Biologics Price Competition and Innovation Act, 351(k)	Federal Food, Drug, and Cosmetic Act, 505(j)

Adapted from (2) GaBi. Small molecule versus biological drugs, 2012; (3) FDA. Overview of the regulatory framework, 2018.

BIOSIMILAR	vs.	GENERIC
Highly similar in structure and biologic activity to reference		Identical active pharmaceutical ingredient to that of reference
No clinically meaningful differences in safety & effectiveness from reference		Bioequivalent to reference, defined as PK values within 80-125%
Interchangeability requires separate FDA-designation		No separate designation for interchangeability
Required: animal (pre-clinical), human (clinical) studies		*Not* required: animal (pre-clinical), human (clinical) studies

(3) FDA. Overview of the regulatory framework, 2018; (4) FDA. Generic drug facts, 2018; (5) FDA. Bioavailability studies, 2019.

BIOSIMILARS LAUNCHED IN THE U.S.

17 of **28** FDA-approved biosimilars are on the market, as of July 2020

Filgrastim (Neupogen®)

Filgrastim-sndz (Zarxio®)
Filgrastim-aafi (Nivestym®)

Pegfilgrastim (Neulasta®)

Pegfilgrastim-jmdb (Fulphila®)
Pegfilgrastim-cbqv (Udenyca®)
Pegfilgrastim-bmez (Ziextenzo®)

Trastuzumab (Herceptin®)

Trastuzumab-anns (Kanjinti™)
Trastuzumab-dkst (Ogivri™)
Trastuzumab-qyyp (Trazimera™)
Trastuzumab-pkrb (Herzuma®)
Trastuzumab-dttb (Ontruzant®)

Bevacizumab (Avastin®)

Bevacizumab-awwb (Mvasi™)
Bevacizumab-bvzr (Zirabev®)

Epoetin (Epogen®, Procrit®)

Epoetin alfa-epbx (Retacrit®)

Rituximab (Rituxan®)

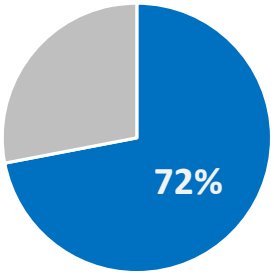
Rituximab-abbs (Truxima®)
Rituximab-pvvr (Ruxience®)

Infliximab (Remicade®)

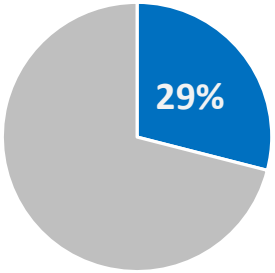
Infliximab-dyyb (Inflectra®)
Infliximab-abda (Renflexis®)

(6) FDA. Biosimilar product information, 2020; (7) AAM. FDA biosimilars approvals, 2020.

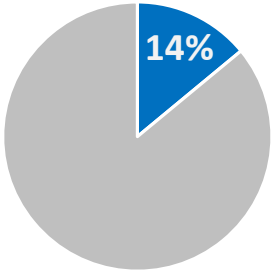
U.S. Biosimilar Utilization Rates in 2020



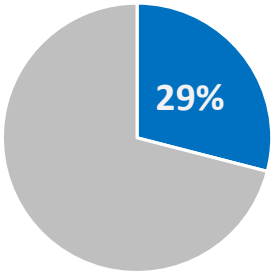
FILGRASTIM
- 1st biosimilar launch: 2015
- Market competitors: 3*



EPOETIN
- 1st biosimilar launch: 2018
- Market competitors: 1



INFLIXIMAB
- 1st biosimilar launch: 2016
- Market competitors: 2

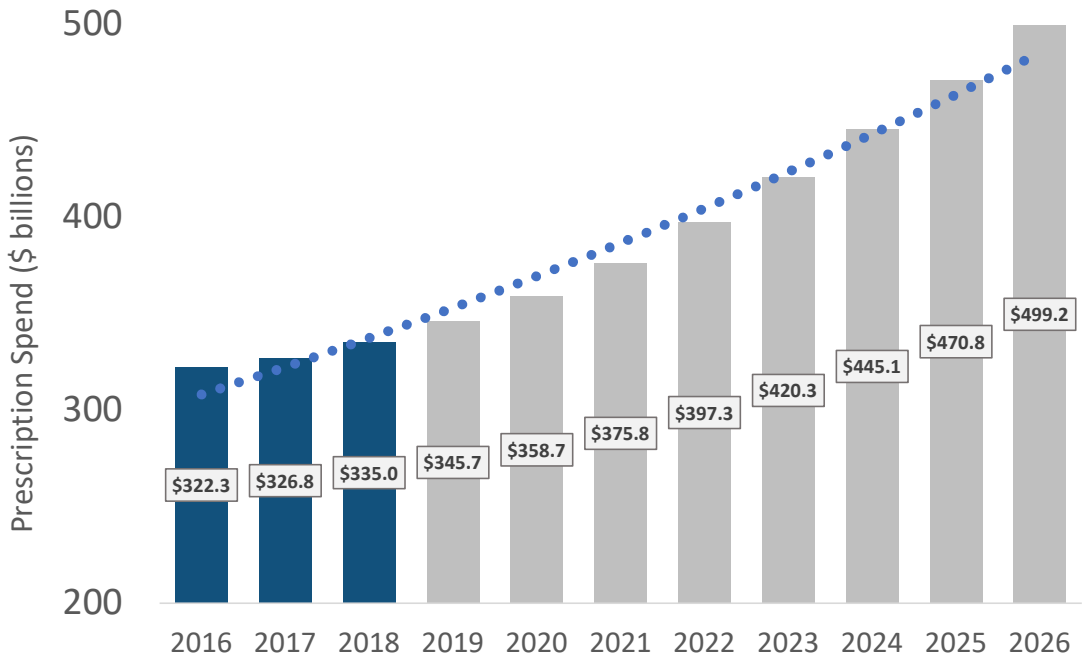


PEGFILGRASTIM
- 1st biosimilar launch: 2018
- Market competitors: 3

*includes tbo-filgrastim

(8) Mehr S, *Biosimilars Review & Report,* 2020.

TRENDS IN U.S. PRESCRIPTION DRUG SPEND



- National prescription spend projected to exceed $400 billion by 2023
- Generics have contributed to almost $2 trillion in 10-year savings to U.S. health system
- Biosimilar products originally projected to reduce U.S. spend by $54 billion over 10 years, but < $1 billion saved between 2015-19

(9) Keehan SP, et al. *Health Affairs,* 2020; (10) AAM. The case for competition, 2019.

BIOSIMILAR BARRIERS

Why is utilization lagging?

KNOWLEDGE GAPS

PRESCRIBERS

Surveys indicate **low confidence** and/or likelihood to prescribe

Doubts about biosimilar safety and efficacy for **extrapolated indications**

Concerns of **immunogenicity risk** of biosimilar vs. reference

PATIENTS

Low overall awareness of biosimilars

Concerns about **side effects**, **efficacy**, and **affordability**

Want to be more **educated** and **involved** in decisions about biosimilar use

(11) Cohen, et al. *Adv Ther*, 2016; (12) Leonard, et al. *J Manag Care Spec Pharm*, 2019; (13) Peyrin-Biroulet L, et al. *J Crohns Colitis*, 2017; (14) Chau et al. *ACR Open Rheumatol*, 2019.

"A Confusing Minefield" of Terms

Naming convention	4-letter suffix at end of nonproprietary name used to differentiate biosimilar from reference product
Extrapolation	Approval for an indication without direct studies in that indication based on sufficient scientific justification
Interchangeable	Regulatory designation for biosimilar that can be substituted for reference; same quality standards required as for biosimilar approval

(3) FDA. Overview of the regulatory framework, 2018; (15) Gottlieb S. Statement from FDA commissioner [press announcement], 2019.

MISINFORMATION CAMPAIGNS

"Interchangeable" implied to designate higher quality

"Highly similar, but not identical"

I am worried that there are either deliberate or unintentional efforts by branded companies to create **confusion**, [which] can potentially undermine consumer confidence in biosimilars in ways that are **untrue**.

Scott Gottlieb, MD
U.S. FDA Commissioner, 2019

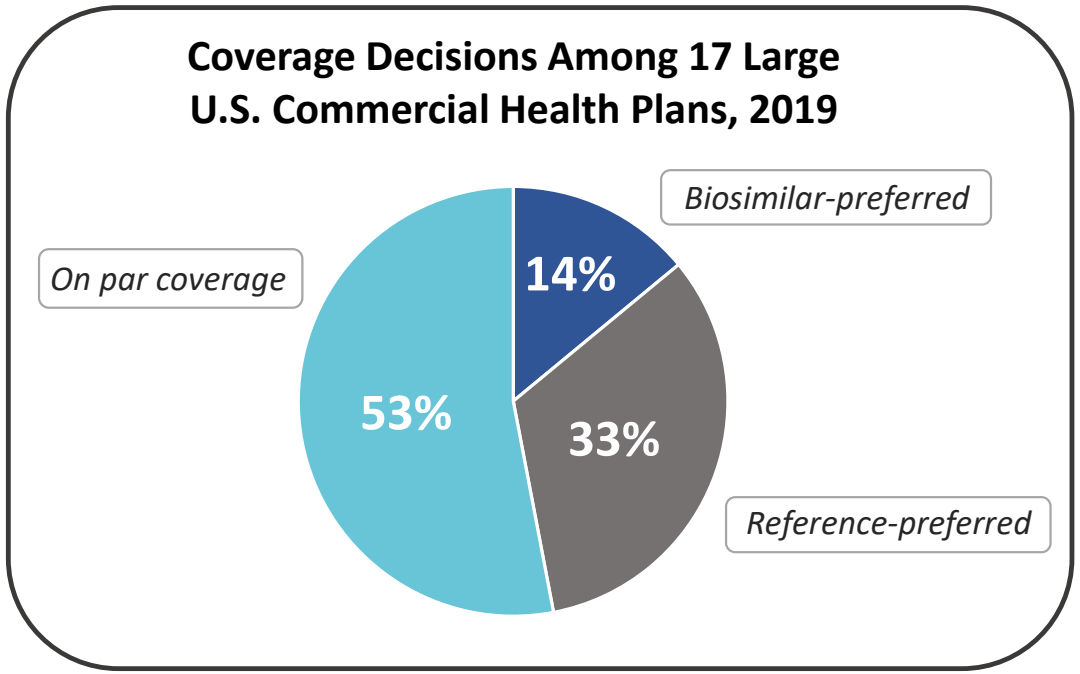
"Non-medical switching"

"Switching drugs is not a good idea"

(16) Awsare S, et al. *Health Affairs Blog, 2019*; (17) Bessette Z. *Journal of Clinical Pathways,* 2019; (18) Cohen H, McCabe D. *StatNews*, 2019.

PAYER POLICIES

- Coverage policies for biologics vary among payers
  - e.g. trial of biosimilar required before reference product will be covered, or vice versa
- Complex to manage when multiple competitors are available and different products are preferred by different payers



(19) Chambers JD, et al. *JAMA,* 2020; (20) Donnelly AJ. *Pharmacy Times*, 2019.

BIOSIMILAR USE STRATEGIES

How do we face the challenges?

STAKEHOLDERS: "TEAM UP"

- Regulations on false or misleading promotional statements
- Patient access and support programs
- Fair payer reimbursement for outpatient and inpatient use
- Out-of-pocket patient costs

(21) McGowan S, *StatNews*, 2020; (22) Greene L, et al. *J Manag Care Spec Pharm*, 2019.

STAKEHOLDERS: "TEAM UP"

- Formulary policies
  - Treatment-naïve
  - Switching from reference
- Electronic health record system tools to streamline workflow
- Prescriber and pharmacy education
  - Switch studies
  - Real-world evidence

(22) Greene L, et al. *J Manag Care Spec Pharm*, 2019; (23) Humphreys SZ. AJMC Center for Biosimilars, 2020.

Europe

10 years of clinical experience show that biosimilars can be used as **safely** and **effectively** in all their approved indications as other biological medicines.

There is also **no reason to believe that harmful immunogenicity should be expected** after switching between highly similar biological medicines.

European Medicines Agency (EMA)

U.S.

Biosimilars go through a rigorous review process and, once approved, are just as **safe** and **effective** as the reference products they are compared to.

Generally, biosimilar medications can be used **whether or not you have been treated first** with the reference product.

Food & Drug Administration (FDA)

(24) EMA. Biosimilars in the EU: information guide, 2019; (25) FDA. Biosimilar basics, 2020.

Real-World Experience

Yale New Haven Health	Boston Medical Center Health System	Providence St. Joseph Health
• 100% adoption of filgrastim-sndz, 100% adoption of pegfilgrastim-cbqv, 65% adoption of infliximab-abda and infliximab-dyyb • Formulary policy – biosimilars considered therapeutically equivalent to reference	• 97% conversion rate of infliximab to infliximab-dyyb – estimated annual savings of $500,000 • Collaboration among multiple stakeholders, champion provider, education campaigns, proactive inventory strategy and prior authorization process	• Nearly $10 million in biologic savings in 2019 • 4 biosimilar-focused initiatives: filgrastim, pegfilgrastim, infliximab, epoetin alfa • Expedited formulary review, EHR-guided prescribing, evaluation of financial benefit across different settings

(23) Humphreys SZ. AJMC Center for Biosimilars, 2020; (26) Woollett G, et al. AMCP Nexus, 2019; (27) Bhat, et al. *J Manag Care Spec Pharm*, 2020.

Kaiser Permanente

Our pharmacists and staff are often the last interaction and serve as a primary point of contact for members throughout the care delivery process

$9.6 billion
in annual drug expenses[4]

$2.3 billion
in annual dispensing expenses[4]

Our Member Reach

543 KP Pharmacy Patient Sites[5]

- 398 Outpatient and
- 45 Inpatient Pharmacies
- \+
- 62 Clinic Administered Sites
- 27 Home Infusion, ASCs, & Specialty
- \+
- 7 Call Center and
- 4 Central Fill Operations

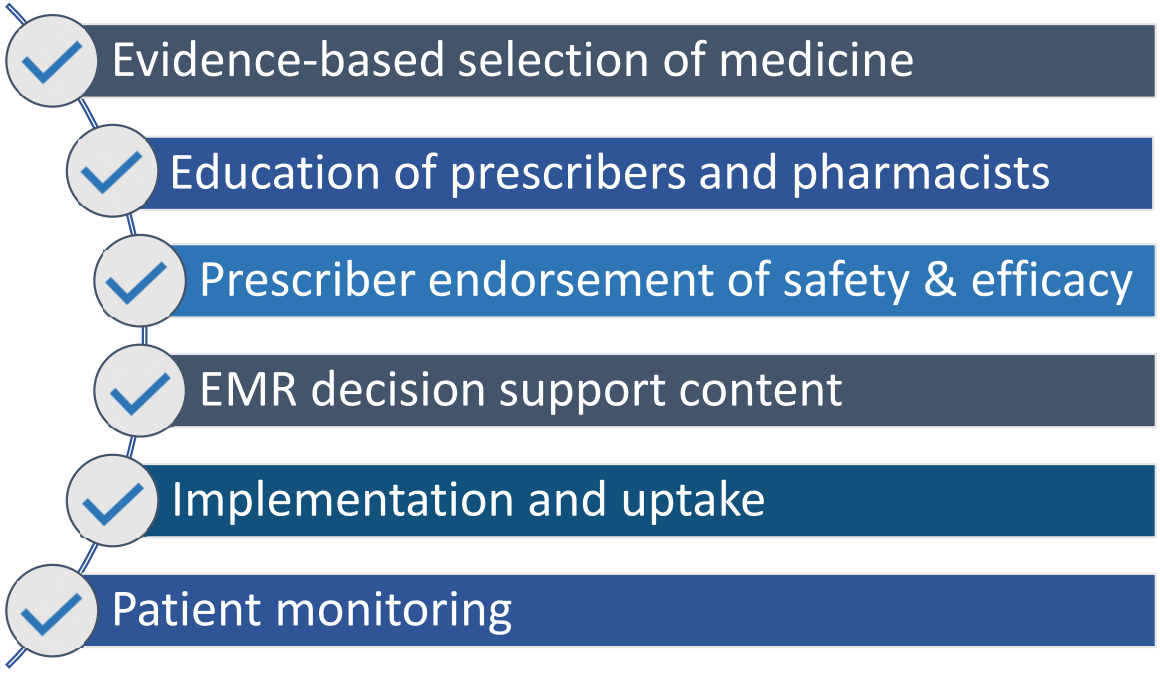
Employing **14,849** KP Pharmacy Staff Members[6]

~206,451+ Daily Member Interactions[7]

One of the highest volume and most frequent member touch points across our Kaiser Permanente network

Note: (1) Data is for outpatient claims only. (2) Inpatient internal claims based on MAR. (3) CAM internal claims only and may be lower than reality since not all clinic meds are documented correctly via MAR.
Source: (4) Total KP Pharmacy Drug Expense and Dispensing Costs 2019 (National Pharmacy Finance); (5) KP Pharmacy Facilities Count (with KP Washington); (6) KP pharmacy Employee Counts - PeopleSoft as of 1/6/2020; (7) Total KP Pharmacy average daily number of members receiving medication [outpatient, inpatient, oncology/infusion], 2019.

KAISER PERMANENTE PROCESS



Education is a pivotal factor
- Ongoing communication
- Materials for both colleagues and patients
- Review of internal and external experiences with biosimilars
- Pharmacovigilance

Adapted from (28) Awsare SV, Chiu T. World Congress of Biosimilars, 2020.

FACILITATING BIOSIMILAR USE

- Pharmacy-physician workgroups design implementation process
  - Development of EHR tools
  - Therapeutic equivalency protocols
  - Inventory strategy
- Educational programming for providers, medical team, and patients
- Communicate with patients prior to implementation
- Clinical pharmacy specialists conduct patient consults and re-education where needed
- Ongoing monitoring of safety and effectiveness

(29) Hubrich K, Smith L. AMCP Nexus, 2018; (30) Gutierrez A. GRx+Biosims Conference, 2019.

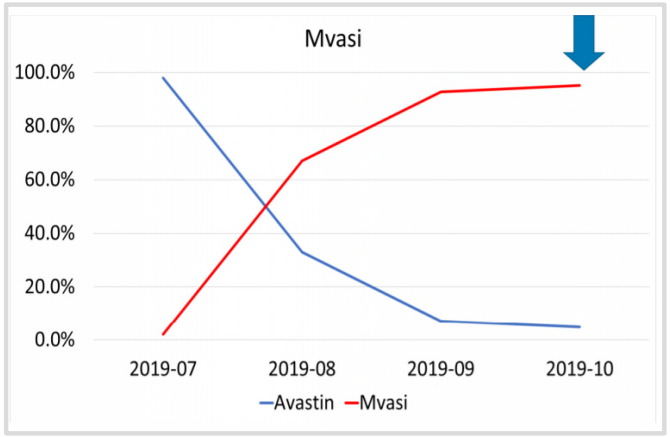
KP Experience with Biosimilars

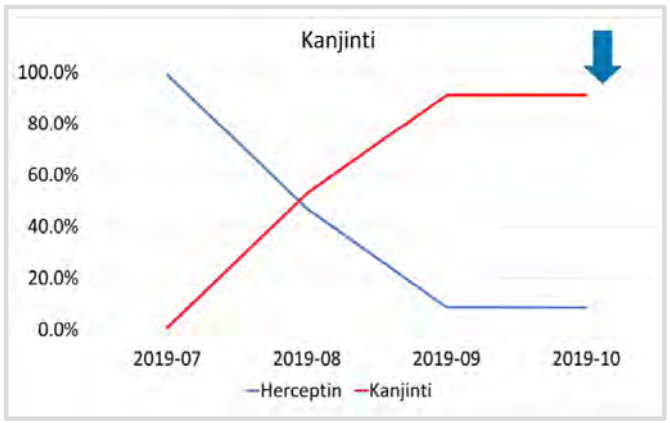
Biosimilars used in treatment-naïve **and** treatment-experienced

80-95% utilization rate of biosimilars versus reference biologic

Most patients **satisfied** or **very satisfied** with switch to a biosimilar

Estimated savings of **$200 million** attributed to use of biosimilars



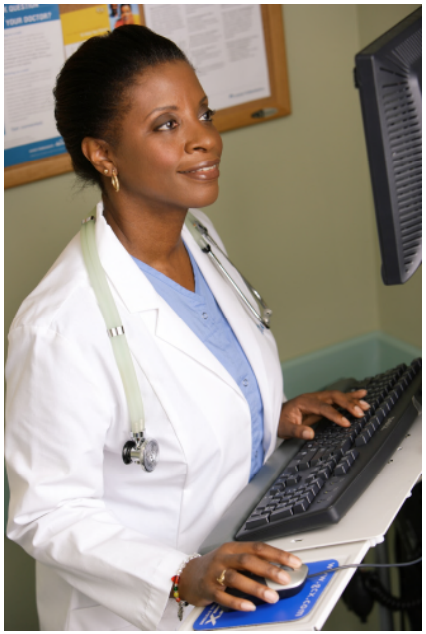


(14) Chau J, et al. *ACR Open Rheumatol,* 2019; (16) Awsare S, et al. *Health Affairs Blog,* 2019; (30) Gutierrez A. GRx+Biosims Conference, 2019.

REAL-WORLD DATA & EVIDENCE

How are biosimilar studies designed?

REAL-WORLD EVIDENCE ON BIOSIMILARS



- Easier and faster to conduct than prospective trials
- Study extrapolated indications
- Comparative groups
- Longer follow-up time
- Larger sample size
- Rare events
- May be used in “interchangeable” application for FDA

(31) Desai RJ, et al. *Pharmacoepidemiol Drug Saf*, 2020.

REAL-WORLD EVIDENCE: CHALLENGES

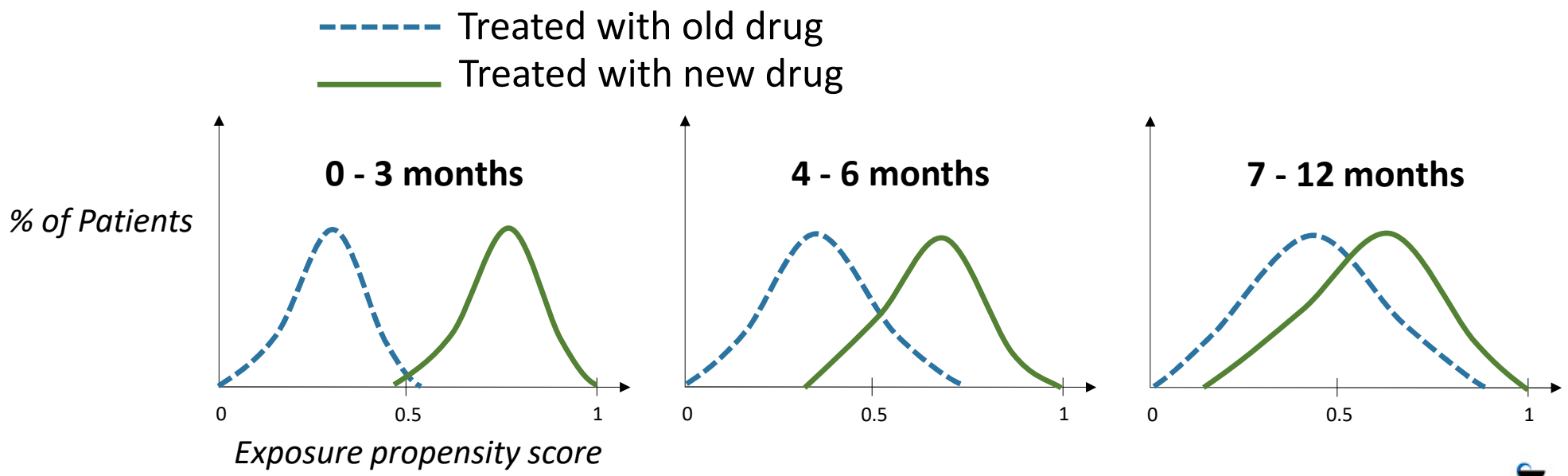
- Data sources – availability, fragmentation
- Lack of resources to conduct study
- Sample size too small
- Selection bias

  e.g. channeling bias, confounding by indication
- Immortal time bias

(31) Desai RJ, et al. *Pharmacoepidemiol Drug Saf*, 2020.

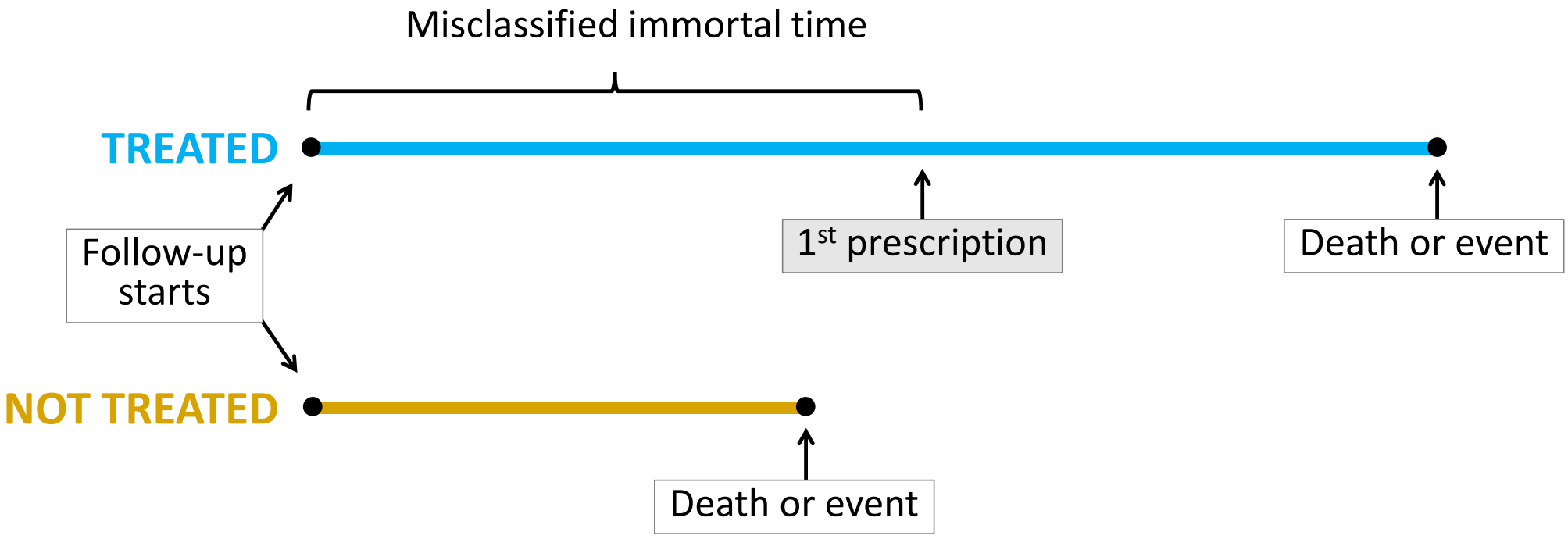
CHANNELING BIAS

Shift in type of patients over time with newly marketed medication



Adapted from (32) Schneeweiss, et al. *Clin Pharmacol Ther,* 2011.

IMMORTAL TIME BIAS



Adapted from (33) Levesque LE, et al. *BMJ,* 2010.

BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM (BBCIC)

- Non-profit, multi-stakeholder research consortium
- Public service initiative focused on conducting rigorous post-marketing observational research to monitor biosimilar products and novel biologics for effectiveness and safety in a real-world setting
- Developed consensus on methodological approaches to conducting biosimilar studies

(26) Woollett G, et al. AMCP Nexus, 2019.

DATA SOURCES

What is available?

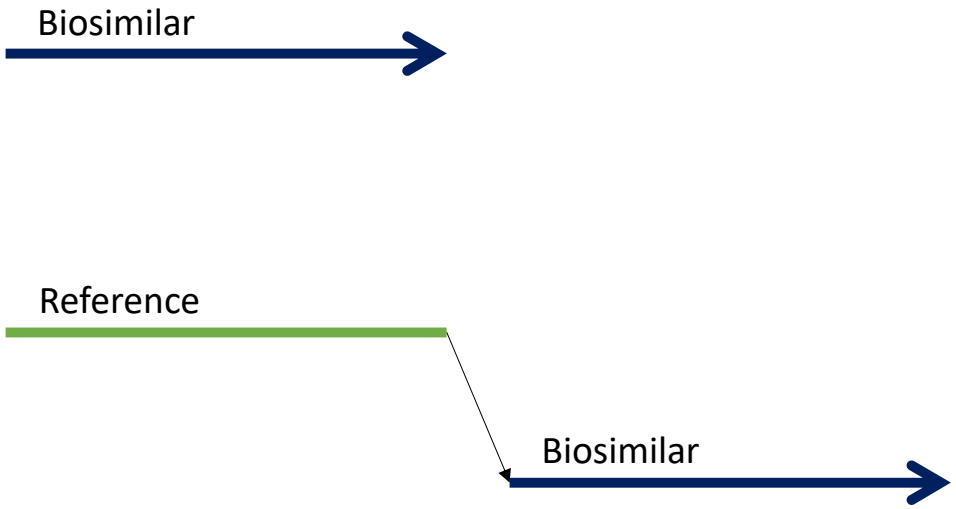
Electronic medical records
Administrative claims
Registries

Patient-reported outcomes

How to get it?

(31) Desai RJ, et al. *Pharmacoepidemiology Drug Saf*. 2020.

STUDY DESIGNS – SINGLE GROUP



<u>Descriptive study of new users</u>

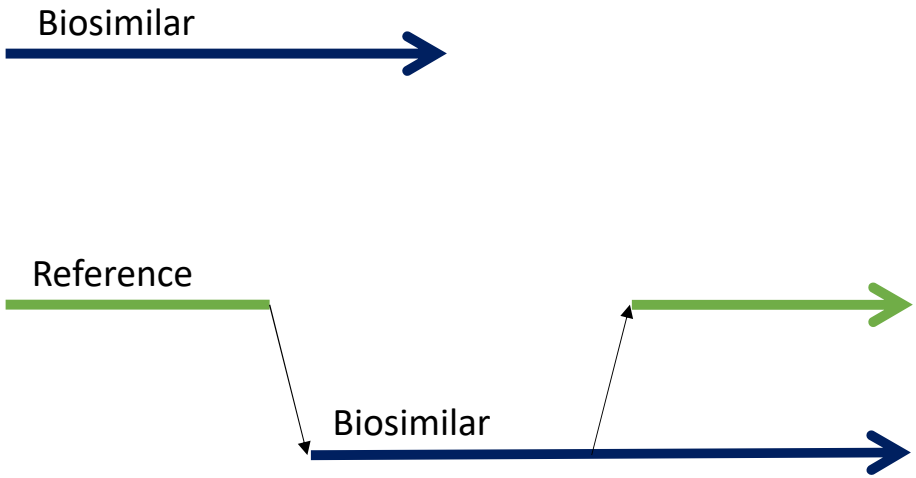
- No comparison group
- Effectiveness and safety

<u>Descriptive study of switchers</u>

- Pre-post design
- Confounding factors: disease progression, treatment phases

(31) Desai RJ, et al. *Pharmacoepidemiology Drug Saf*. 2020.

STUDY DESIGNS – SINGLE GROUP



<u>Descriptive study of new users</u>

- No comparison group
- Effectiveness and safety

<u>Descriptive study of switchers</u>

- Switch back to reference product

(31) Desai RJ, et al. *Pharmacoepidemiology Drug Saf*. 2020.

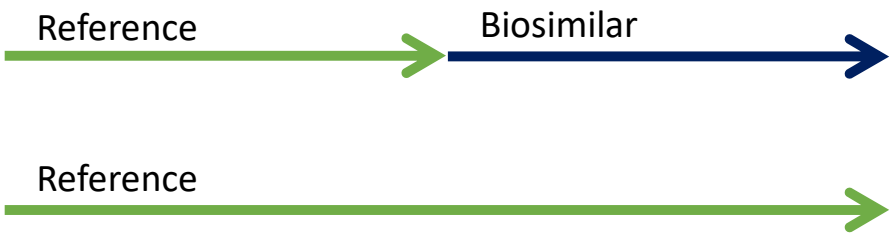
STUDY DESIGNS – COMPARATOR GROUPS

<u>Comparative study of new users</u>

- Channeling bias
- Consider matching
  e.g. propensity score matching
- Non-medical switch: need historical reference product users

(31) Desai RJ, et al. *Pharmacoepidemiology Drug Saf*. 2020.

STUDY DESIGNS – COMPARATOR GROUPS



<u>Comparative study of switchers</u>

- Non-switcher as comparison
- Selection bias – why were patients switched?
- Immortal time bias – match disease severity, length of disease, length of time on reference product

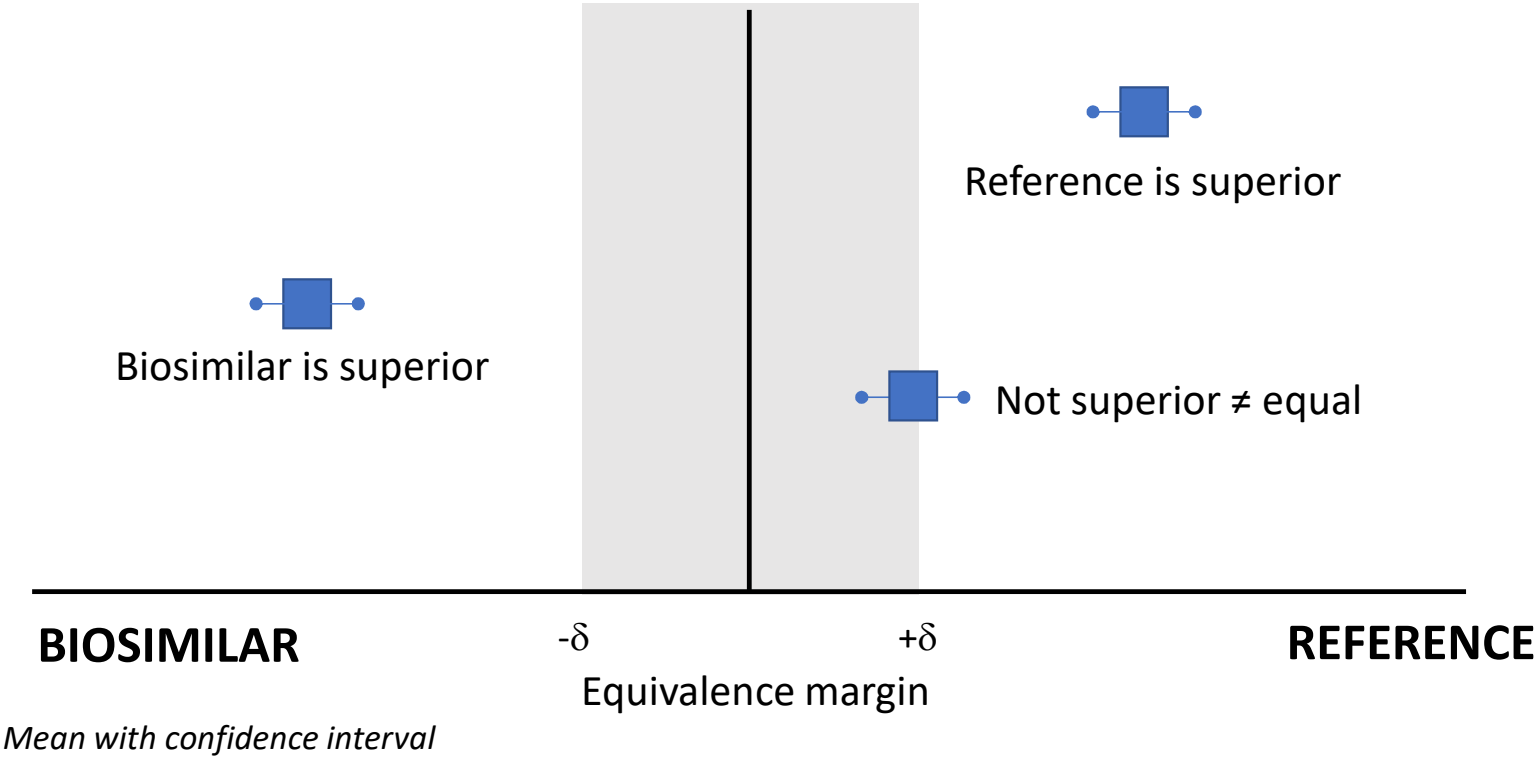
(31) Desai RJ, et al. *Pharmacoepidemiology Drug Saf*. 2020.

OUTCOMES

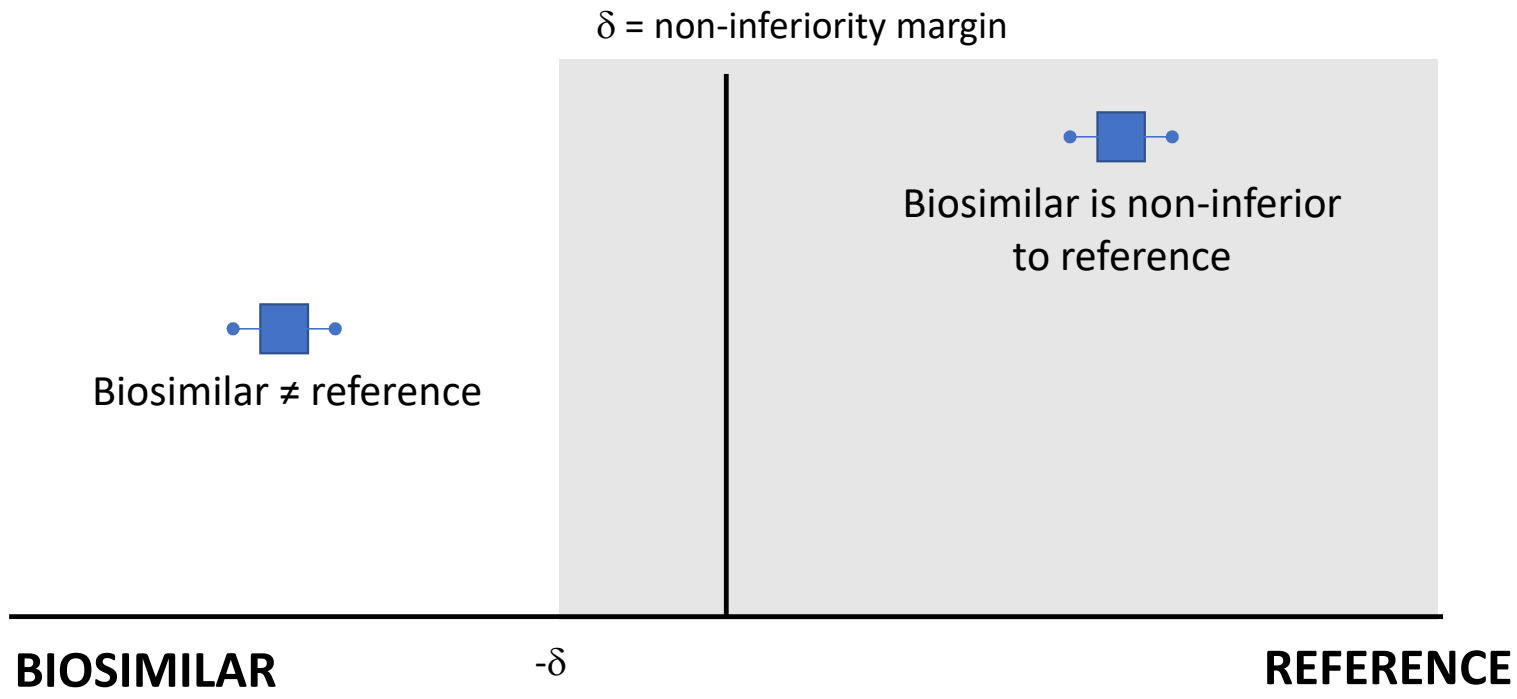
- Clinical effectiveness
- Immunogenicity
- Safety
- Utilization
- Effect of confounding factors

(31) Desai RJ, et al. *Pharmacoepidemiology Drug Saf*. 2020.

ANALYSIS

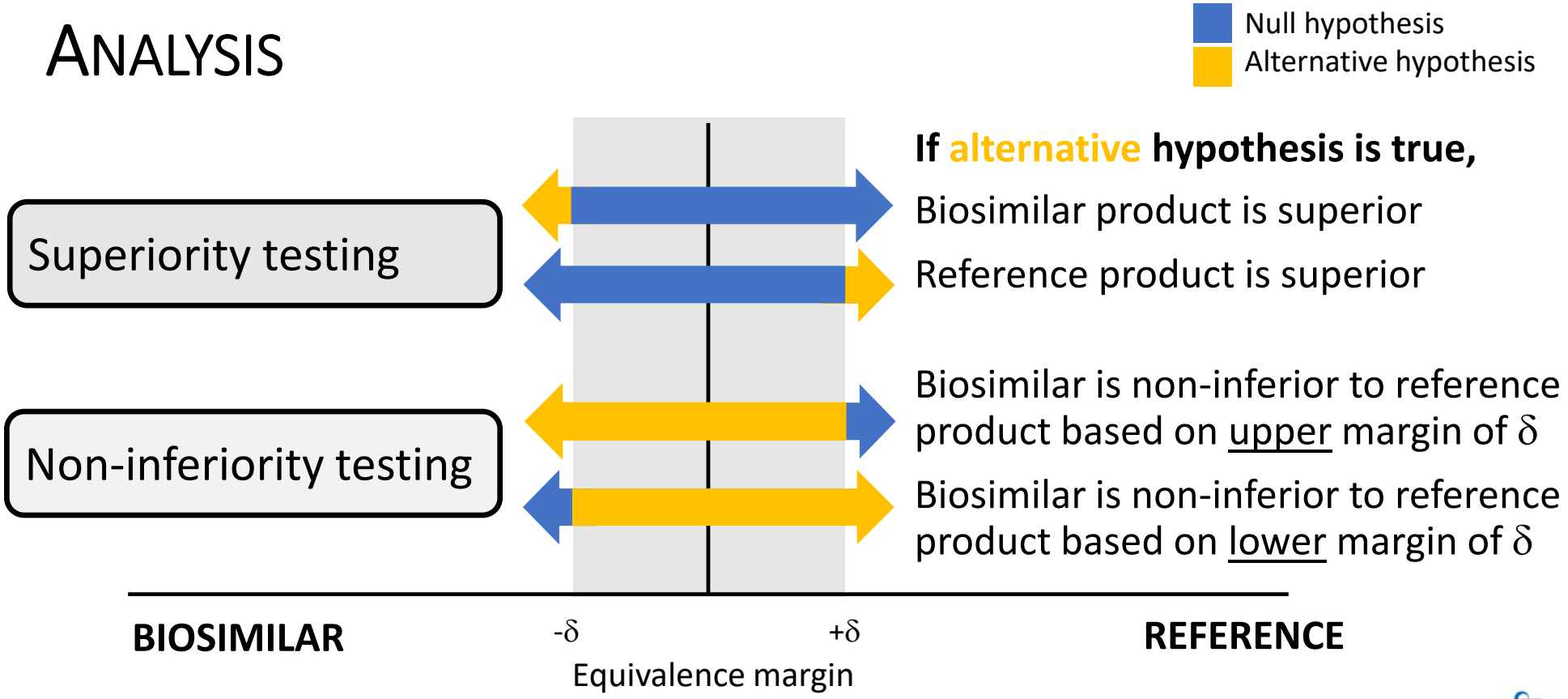

Reference is superior
Biosimilar is superior
Not superior ≠ equal
BIOSIMILAR
-δ
+δ
REFERENCE
Equivalence margin
Mean with confidence interval

ANALYSIS – NON-INFERIORITY



Mean with confidence interval

ANALYSIS


Null hypothesis
Alternative hypothesis
Superiority testing
Non-inferiority testing
If alternative hypothesis is true,
Biosimilar product is superior
Reference product is superior
Biosimilar is non-inferior to reference product based on upper margin of δ
Biosimilar is non-inferior to reference product based on lower margin of δ
BIOSIMILAR
-δ
+δ
REFERENCE
Equivalence margin

REAL-WORLD STUDIES

JOURNAL OF
ONCOLOGY
PHARMACY
PRACTICE

Original Article

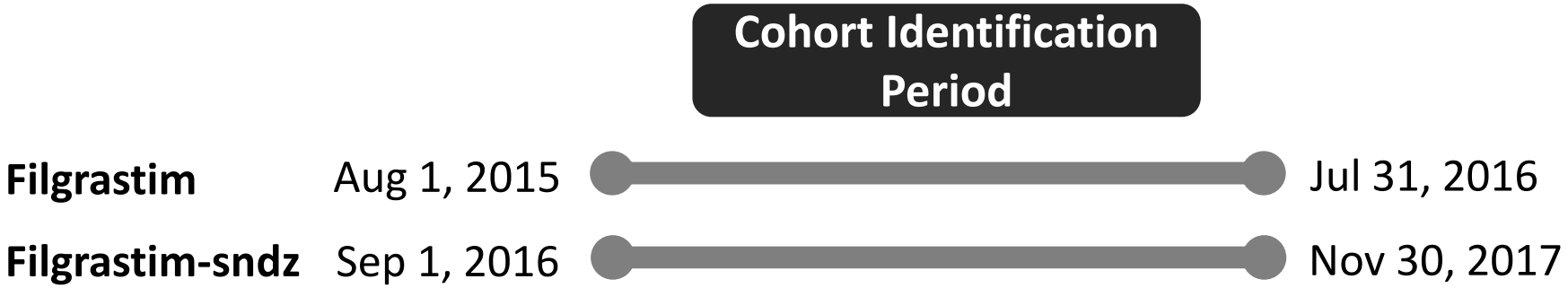
Efficacy of a conversion from filgrastim to filgrastim-sndz in stem cell transplant patients undergoing mobilization

Lauren D Curry[1], Brandi Anders[1], Emily V Dressler[2] and LeAnne Kennedy[1]

(34) Curry LD, et al. *J Oncol Pharm Practice*. 2020.

METHODS – STUDY DESIGN

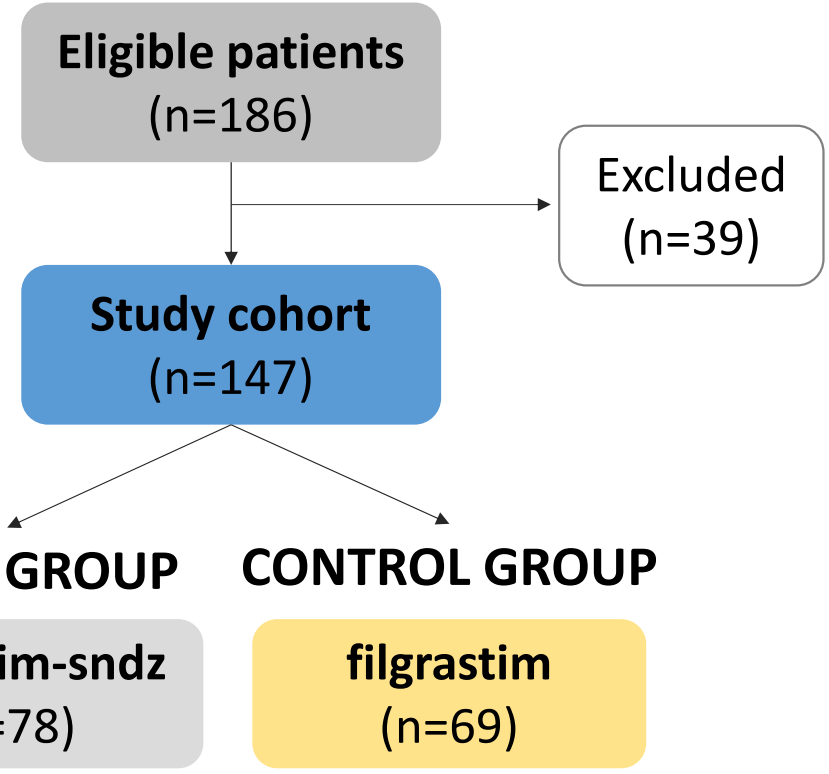
Retrospective observational non-inferiority study



Primary outcome

- Number of CD_{34} stem cells collected during apheresis

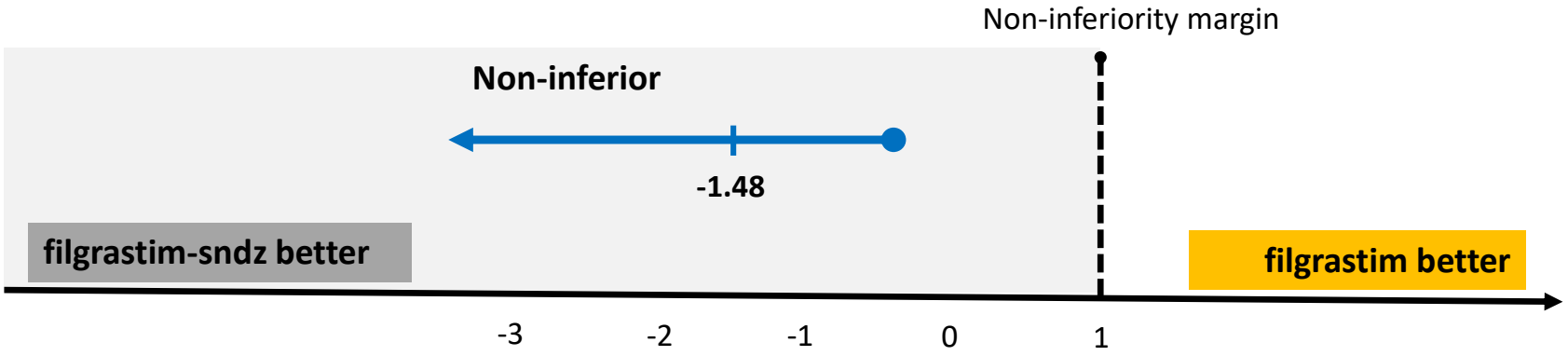
COHORT FLOW DIAGRAM



Baseline age, weight, and diagnosis balanced between the 2 groups

RESULTS – PRIMARY OUTCOME

	filgrastim-sndz (n=78)	filgrastim (n=69)	*p*-value
Mean number of CD_{34} cells collected	**8.86 x 10^6**	**7.38 x 10^6**	**0.0006**



Difference in number of CD_{34} cells (x 10^6) collected during stem cell transplant mobilization

BioDrugs
https://doi.org/10.1007/s40259-020-00409-y

ORIGINAL RESEARCH ARTICLE

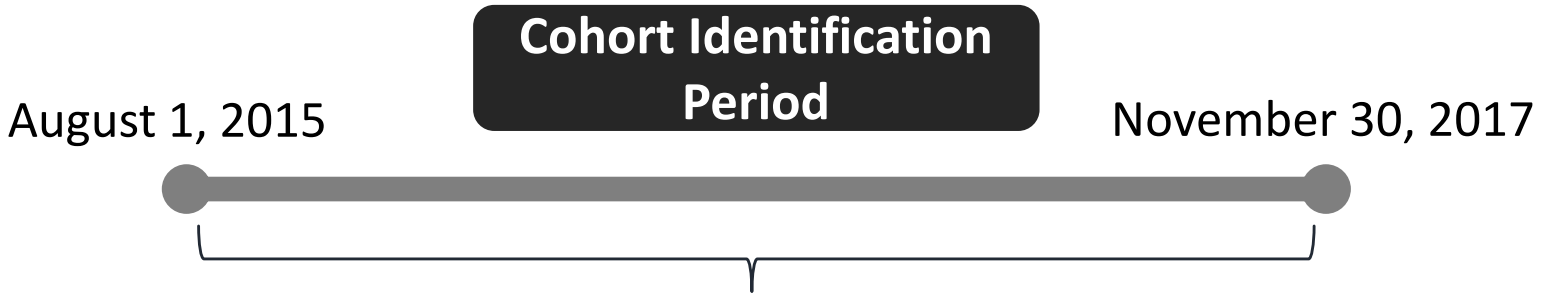
Effectiveness of Switching from Reference Product Infliximab to Infliximab-Dyyb in Patients with Inflammatory Bowel Disease in an Integrated Healthcare System in the United States: A Retrospective, Propensity Score-Matched, Non-Inferiority Cohort Study

Stephanie L. Ho[1] · Fang Niu[2] · Suresh Pola[3] · Fernando S. Velayos[4] · Xian Ning[1] · Rita L. Hui[5]

(35) Ho SL, et al. *BioDrugs*. 2020.

METHODS – STUDY DESIGN

Retrospective, non-inferiority study utilizing propensity score matching



Index Dates

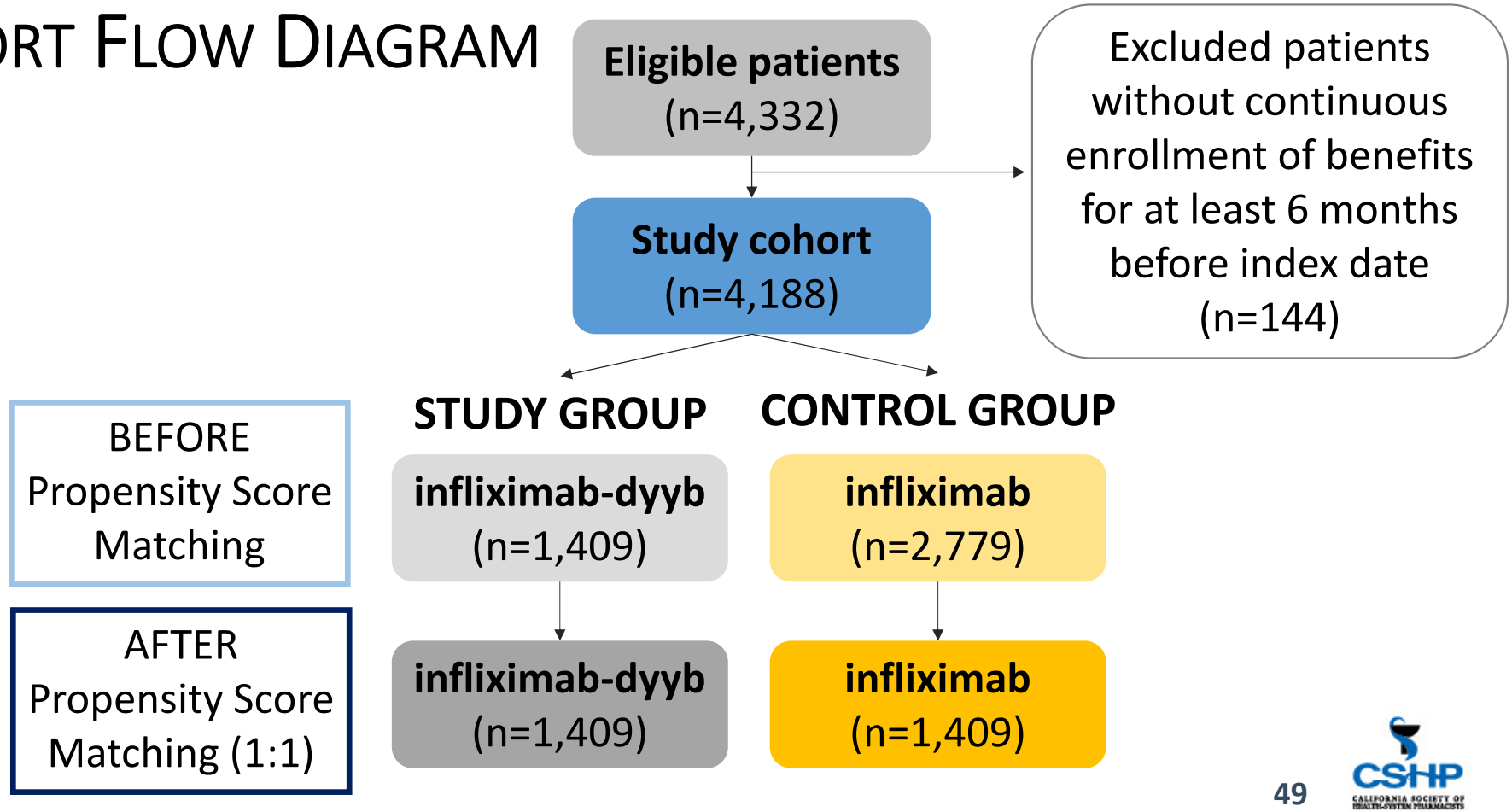
- Control group:
  Date of an infliximab infusion
- Study group:
  Date of first infliximab-dyyb infusion

Follow-Up

Whichever occurred first:

- Death
- End of membership
- Switching therapy
- Up to 9 months

COHORT FLOW DIAGRAM

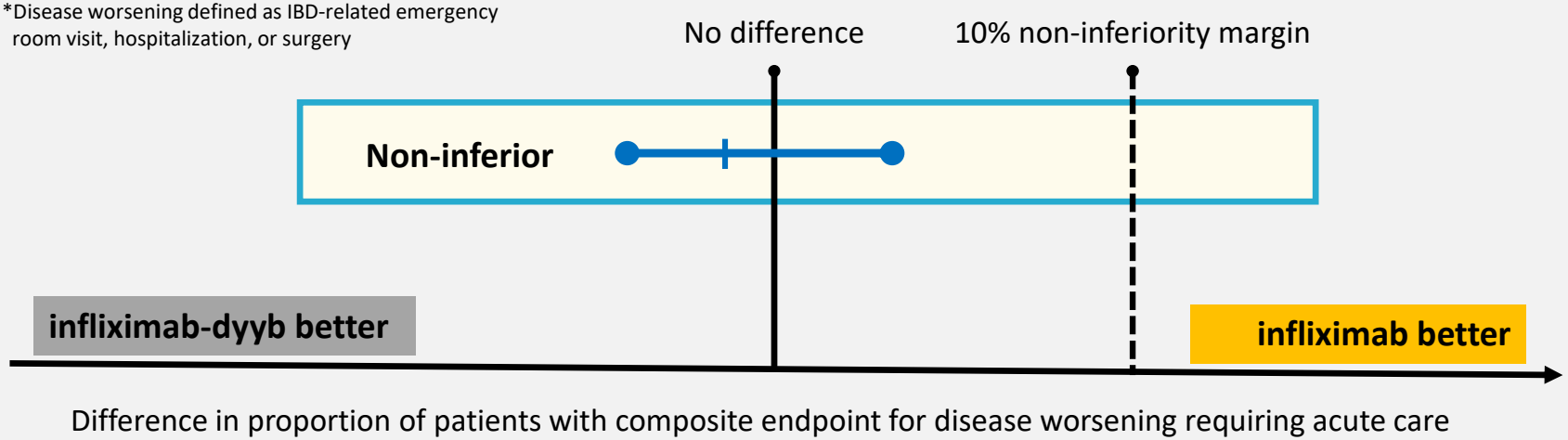


RESULTS – PRIMARY OUTCOME

Non-inferiority

	infliximab-dyyb (n=1,409)	infliximab (n=1,409)	Non-inferiority *p*-value
Composite measure of disease worsening requiring acute care*, n (%)	**144 (10.2)**	**245 (17.4)**	**<0.01**

*Disease worsening defined as IBD-related emergency room visit, hospitalization, or surgery



CONCLUSION

- Biosimilars represent an opportunity to lower health care costs through enhanced competition in the U.S. biologics market
- Barriers for acceptance of biosimilars include skepticism toward available clinical data and misinformation campaigns regarding safety
- Education, communication, and collaboration among stakeholders (e.g. providers, pharmacists, patients, payers) are key strategies to drive utilization of biosimilars
- Collection of real-world data can promote understanding and confidence in the use of biosimilars

ASSESSMENT QUESTION

Which of the following is a barrier to health system adoption and utilization of biosimilar products?

a) No biosimilars currently available on the U.S. market

b) Significant evidence of safety issues with biosimilars

c) Knowledge gaps among providers and patients

ASSESSMENT QUESTION

Education of health care professionals, including review of real-world data, is a strategy that can promote health system adoption and utilization of biosimilar products.

a) True

b) False

ASSESSMENT QUESTION

Which is NOT a type of bias found in real-world evidence (RWE)?

a) Immortal time bias

b) Recall bias

c) Channeling bias

ASSESSMENT QUESTION

Non-inferiority study designs are used to evaluate biosimilars.

a) True

b) False

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SESSION CODE: