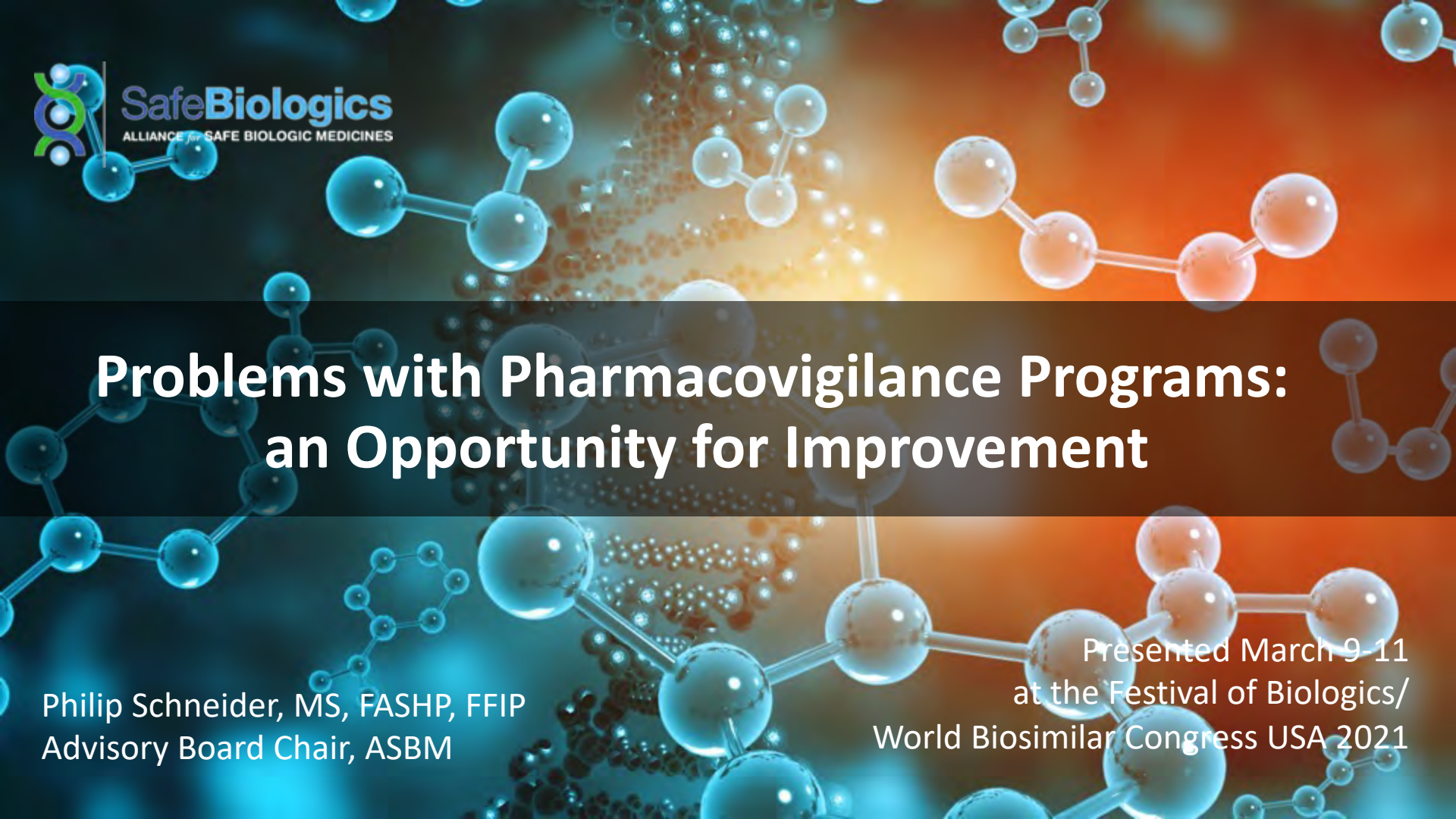


Problems with Pharmacovigilance Programs: an Opportunity for Improvement

Philip Schneider, MS, FASHP, FFIP
Advisory Board Chair, ASBM

Presented March 9-11
at the Festival of Biologics/
World Biosimilar Congress USA 2021

Introduction

- **Philip Schneider, MS, FASHP, FFIP**
- Advisory Board Chair, Alliance for Safe Biologic Medicines
- Past Vice President, International Pharmaceutical Federation (FIP)
- Past-President, American Society of Health-system Pharmacists
- Professor of Pharmacy, Ohio State University

About ASBM

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

Formed in 2010 with the passage of the Affordable Care Act (ACA) and Biosimilar Price Competition and Innovation Act (BPCIA); with the goal of keeping patient safety at the forefront of biosimilar policy discussions.

ASBM's Steering Committee is composed entirely of patient and physician member organizations.

- PATIENT ADVOCATES
- PHYSICIANS
- PHARMACISTS
- RESEARCHERS
- MANUFACTURERS (INNOVATOR & BIOSIMILAR)

LYMPHOMA COALITION
Worldwide Network of Lymphoma Patient Groups

American Gastroenterological Association

CSRO
Coalition of State Rheumatology Organizations

More than 130 organizations spread across six continents; the More than 130 organizations spread across six continents; the majority of these are patient groups, including several patient coalitions.

ASBM Physician and Pharmacist Surveys

U.S. Physicians
2012: n=376
2015 n=400
2015: n=400
2019: n=202
2021 n= 400

U.S. Pharmacists
2015 n=401

Latin American Physicians
(Argentina, Brazil, Colombia, Mexico)
2015: n=399

Canadian Physicians
2014: n=427
2017: n=427
2021 (planned)

European Physicians
(France, Italy, Germany, Spain, Switzerland, UK)
2013: n=470
2019: n=579

Australian Physicians
2016: n=160

All surveys available at www.SafeBiologics.org/surveys

Sharing Perspectives With Regulators

WORLD HEALTH ORGANIZATION INN CONSULTATIONS
(2013-2022)

AUSTRALIAN DEPARTMENT OF HEALTH,
THERAPEUTIC GOODS ADMINISTRATION (2017)

HEALTH CANADA, CANADIAN HEALTH MINISTRY (2017)

INTERNATIONAL CONFERENCE OF DRUG REGULATORY
AUTHORITIES (ICDRA) (2016, 2018)

ASBM INTERNATIONAL REGULATOR FORUMS
ON NOMENCLATURE HARMONIZATION
(FDA, HEALTH CANADA, WHO) 2018-2019

EU COMMISSION/EMA BIOSIMILARS MEETING (2019)

U.S. FDA/FEDERAL TRADE COMMISSION WORKSHOP ON BIOSIMILAR COMPETITION
(MARCH 2020)

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

World Health Organization

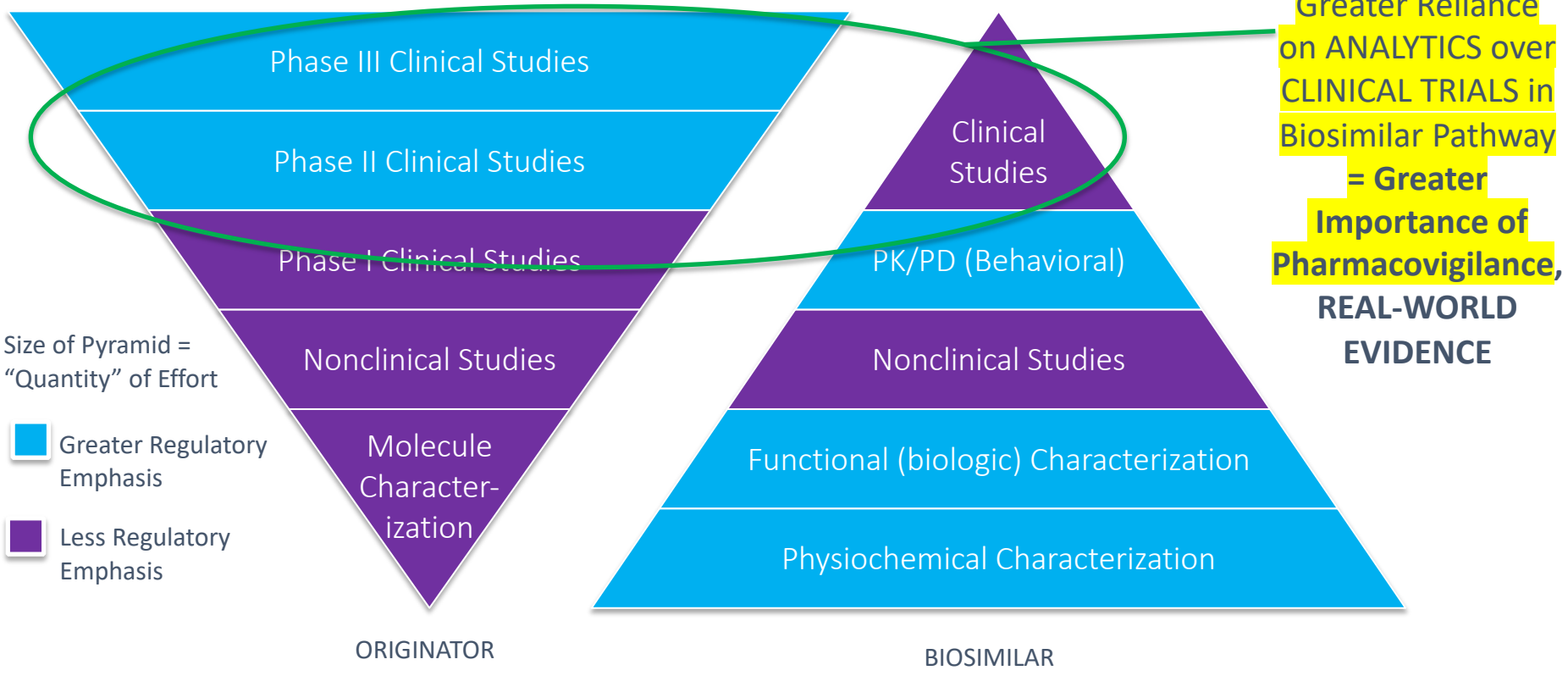
Health Canada Santé Canada

FDA

Australian Government
Department of Health
Therapeutic Goods Administration

ANVISA

Approval Pathway: Originator vs. Biosimilar



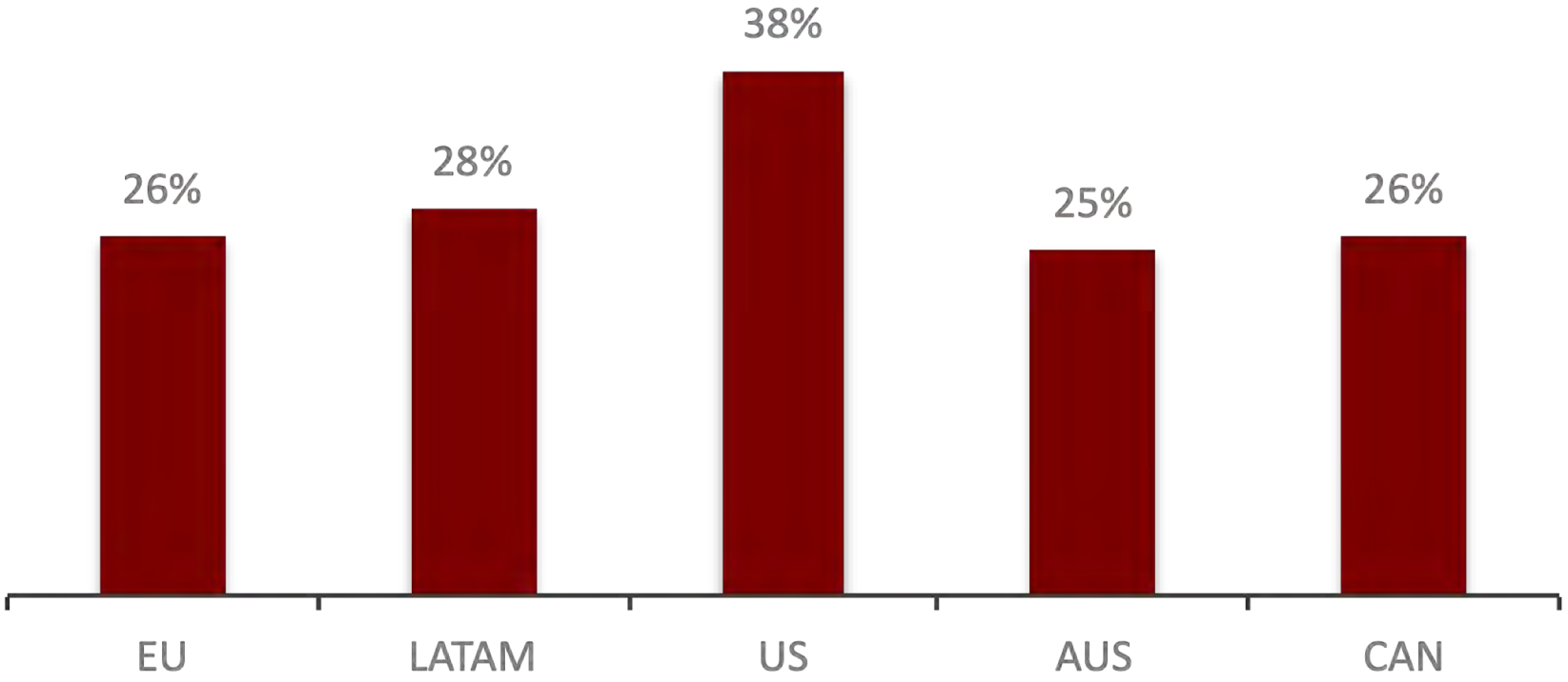
Challenge: Originator Product and Biosimilars share an WHO-assigned International Proprietary Name (INN)

- **For example, all the products on the right use the INN "infliximab"**
- Trade names differ from country to country.
- **This can become confusing and result in:**
  - **Misattribution of adverse events**
  - **Inadvertent or inappropriate substitution**
  - **Inaccurate patient records**
  - **Inability to do targeted recalls**

Manufacturer	Trade Name(s)
Janssen	Remicade
Amgen	Avsola
BCD-055	Biocad
Celltrion/Hospira (Pfizer)	Remsima/Inflectra/Flammegis/Ifixi
Epirus	Infimab
MabTech/Sorrento	STI-002
MabTech/Sorrento	CMA-B008
Nichi-Iko	NI-071
Nippon Kayaku	Infliximab BS
Ranbaxy	BOW015
Samsung Bioepis	Flixabi
Sandoz	Zessly
Shanghai Biomabs	Baimaibo

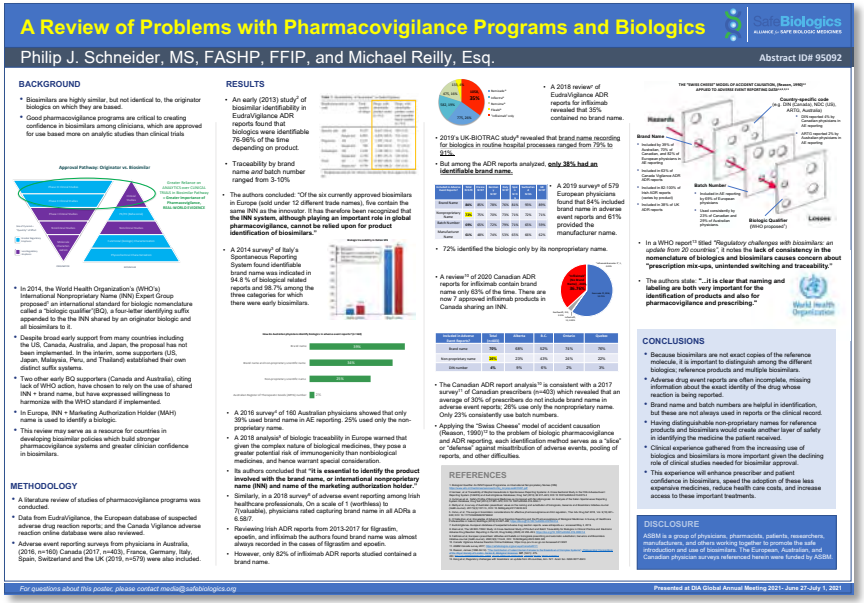
ASBM Surveys (2013-2017): Percent of Physicians Using Only INN when Reporting Adverse Events.

(This could result in improper attribution or pooling of adverse events.)



DIA 2021 Poster: “A Review of Problems with Global Pharmacovigilance” (June 27-July 1)

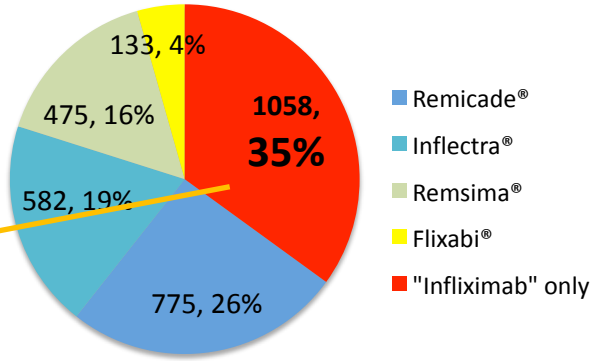
- Examined published literature on identifiability of biologic products.
- Focused on problems in adverse event reporting
- Found that identifiability to the product level is important to physicians.
- **Yet recording of brand names in adverse event reporting varies wildly from country to country, and between practice settings.**
- **More than a third of AE reports in Canada and Europe do not contain brand name.**

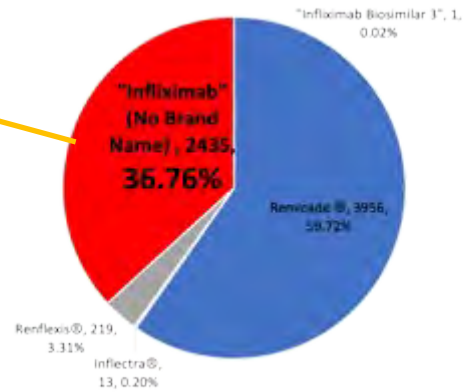


See a video walkthrough of the poster here…

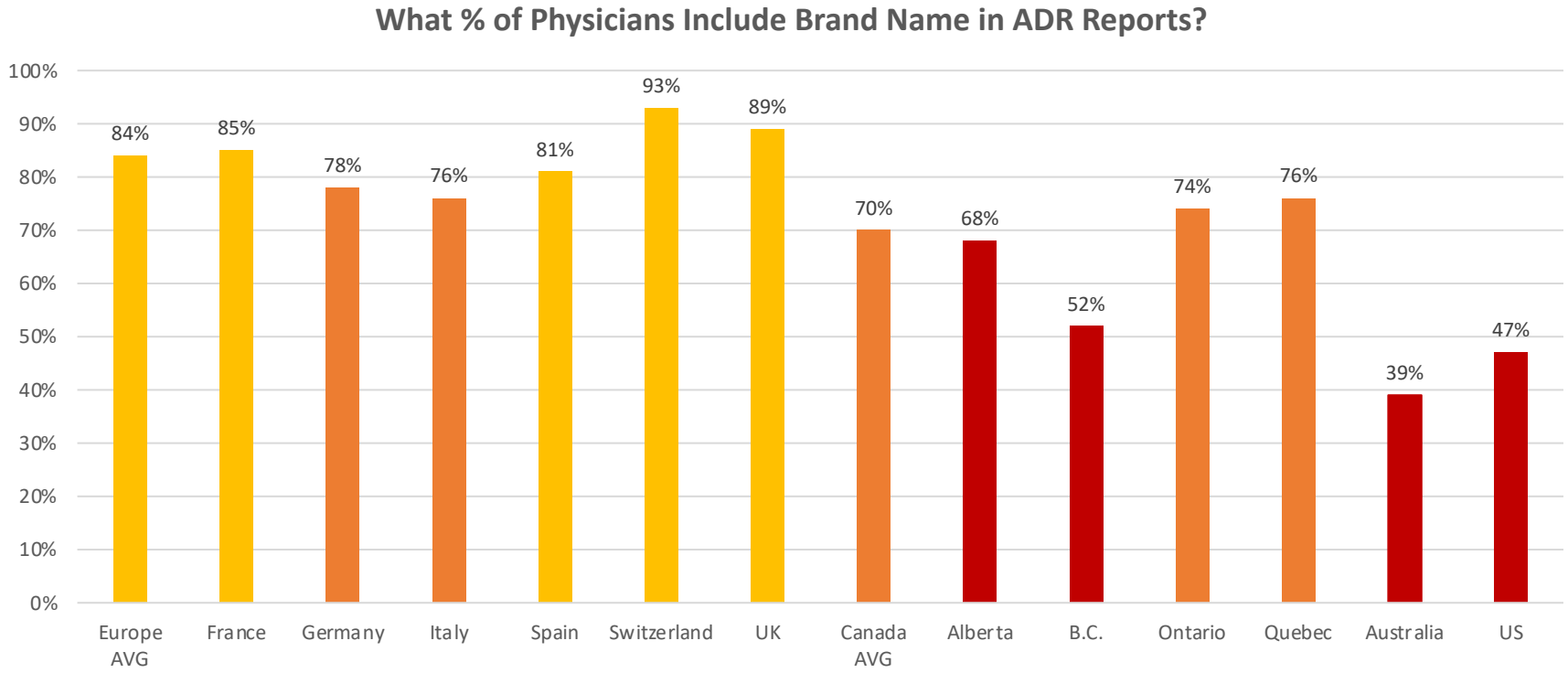
Brand Name Recording in ADR Reports: Wide Variation

- 2018 Irish ADR reports for infliximab: **18% missing brand name**
- A 2018 review of EudraVigilance ADR reports for infliximab revealed that **35% contained no brand name.**
- A review of 2020 Canadian ADR reports for infliximab **are missing brand name 37% of the time.**
- 2019 UK BIOTRAC study: **only 38% of ADR Reports had an identifiable brand name.**





Brand Name Recording by Physicians: ASBM Survey Data

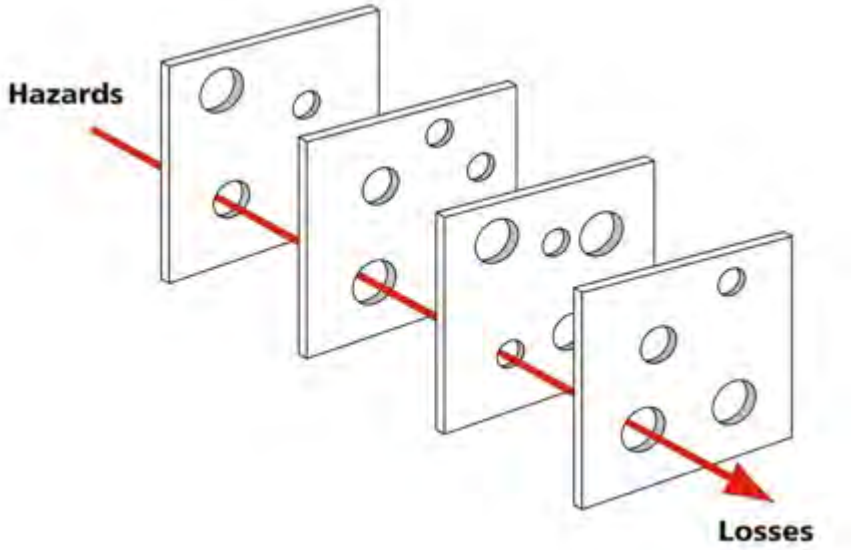


Source: Australia, Europe, and US physician surveys (2016-2019) www.safebiologics.org/surveys

Safety Science: High Reliability Systems

- High-reliability systems need multiple checks: airlines, healthcare, medication systems.

- The “Swiss cheese model” from industrial psychologist James Reasons is used worldwide to design high reliability safety systems.



- Each “slice” (“defense”) is a protection against hazardous conditions becoming an accident.

The WHO's INN Expert Group recognized these problems long ago…and proposed a solution.

THE "SWISS CHEESE" MODEL OF ACCIDENT CAUSATION, (Reason, 1990)[12] APPLIED TO ADVERSE EVENT REPORTING DATA[4,6,8,9,11]