



Unlocking Real-World Data with AI



Understanding Real-World Data and its potential

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Declaration of interest

- Community pharmacy owner
- Independent expert in pharmacoepidemiology and RWE, founder of METIS RW
- Consultant at Bordeaux PharmacoEpi, a research platform from the University of Bordeaux, which conducts real-world studies in collaboration with public and private partners in compliance with the ENCePP code of conduct
- Consulting activities for Reckitt Benckiser, Janssen



Definitions



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- **Real-world data (RWD)** are **data relating to patient health status and/or the delivery of health care, routinely collected** from a variety of sources.
- **Real-world evidence (RWE)** is the clinical evidence about the usage, and potential benefits or risks of a medical product derived from analysis of real-world data.

Types of real-world data



Claims and billing activity



Electronic health records (EHRs)



Patient-reported outcomes

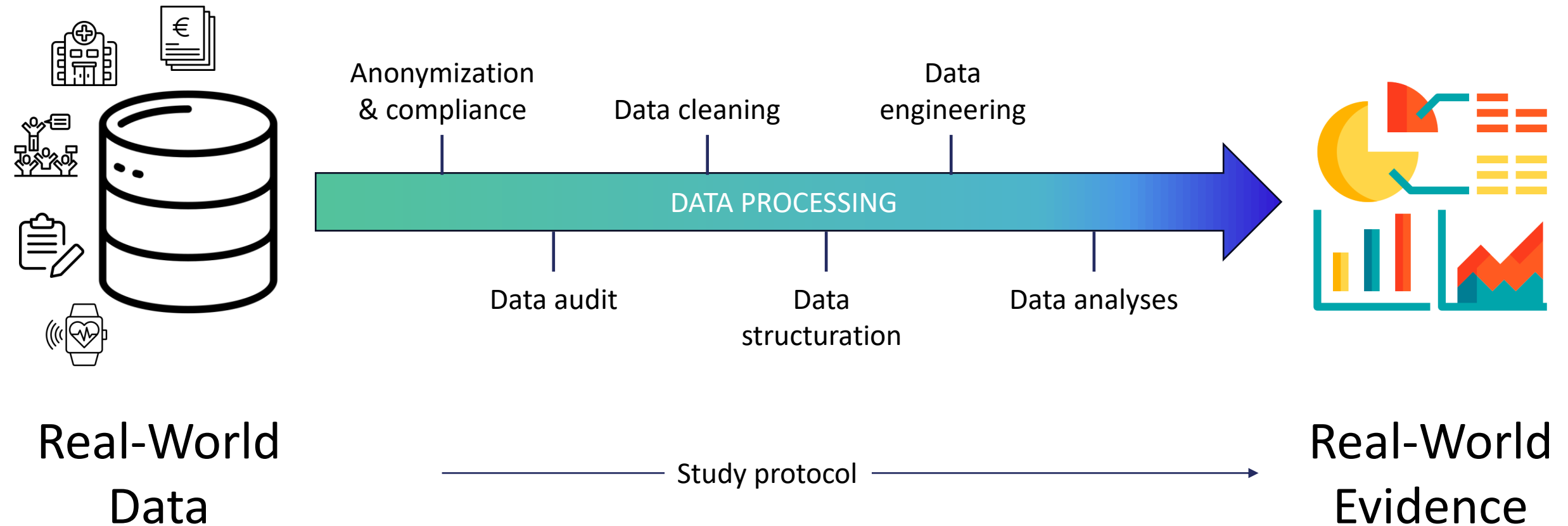


Disease or product registries



Biometric monitoring sources (e.g., smartwatches)

RWD to RWE



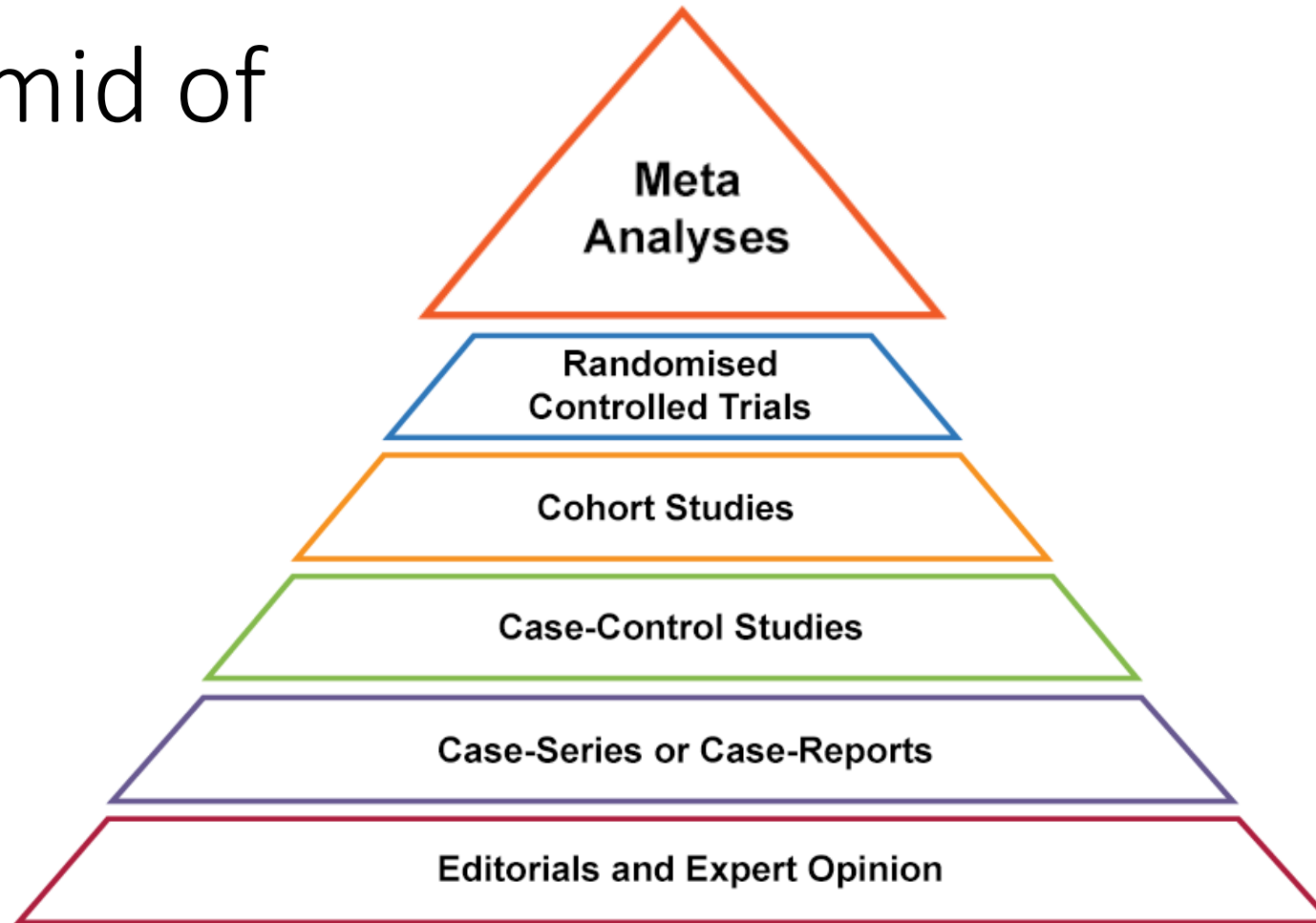
The pyramid of evidence



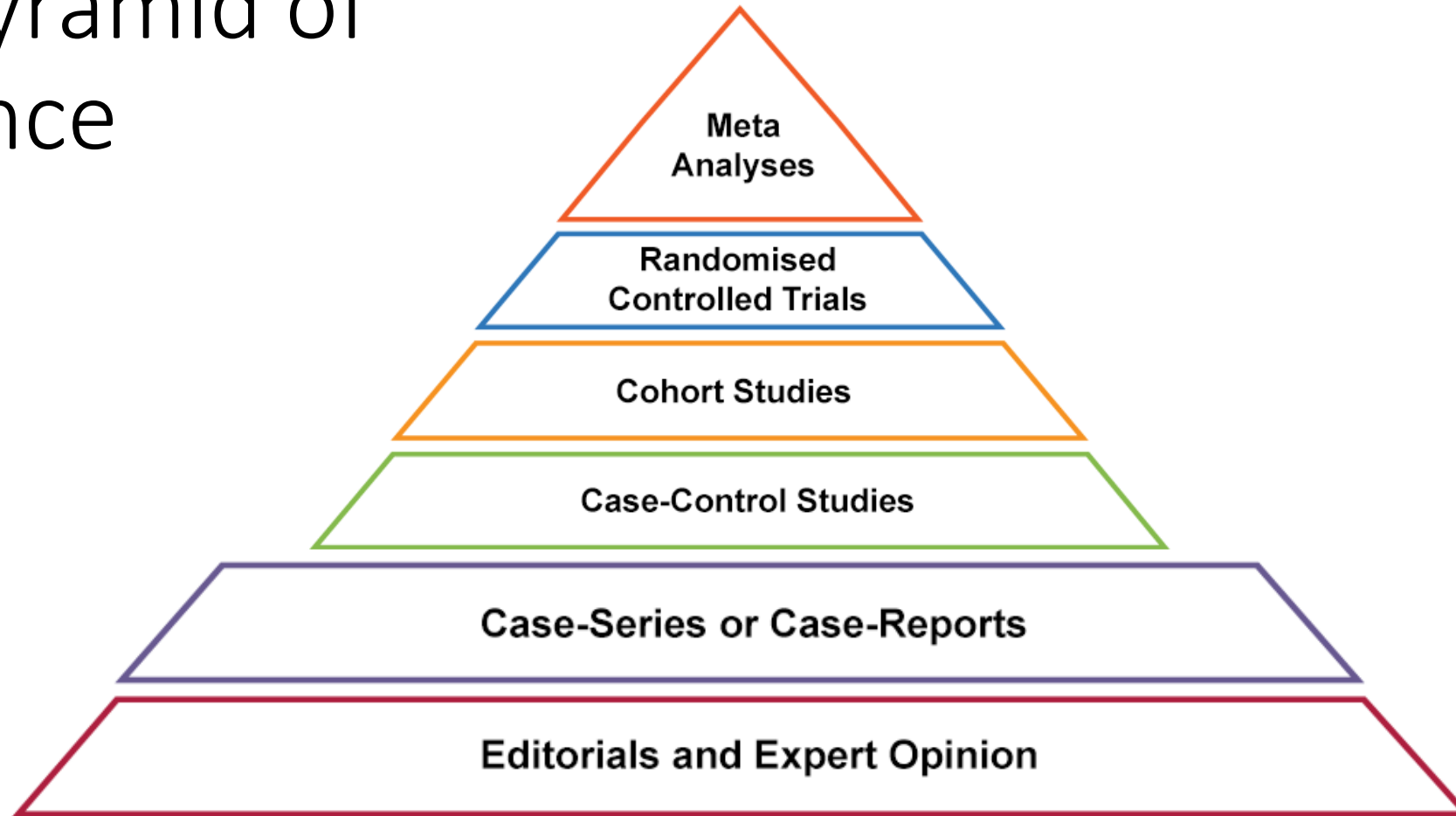
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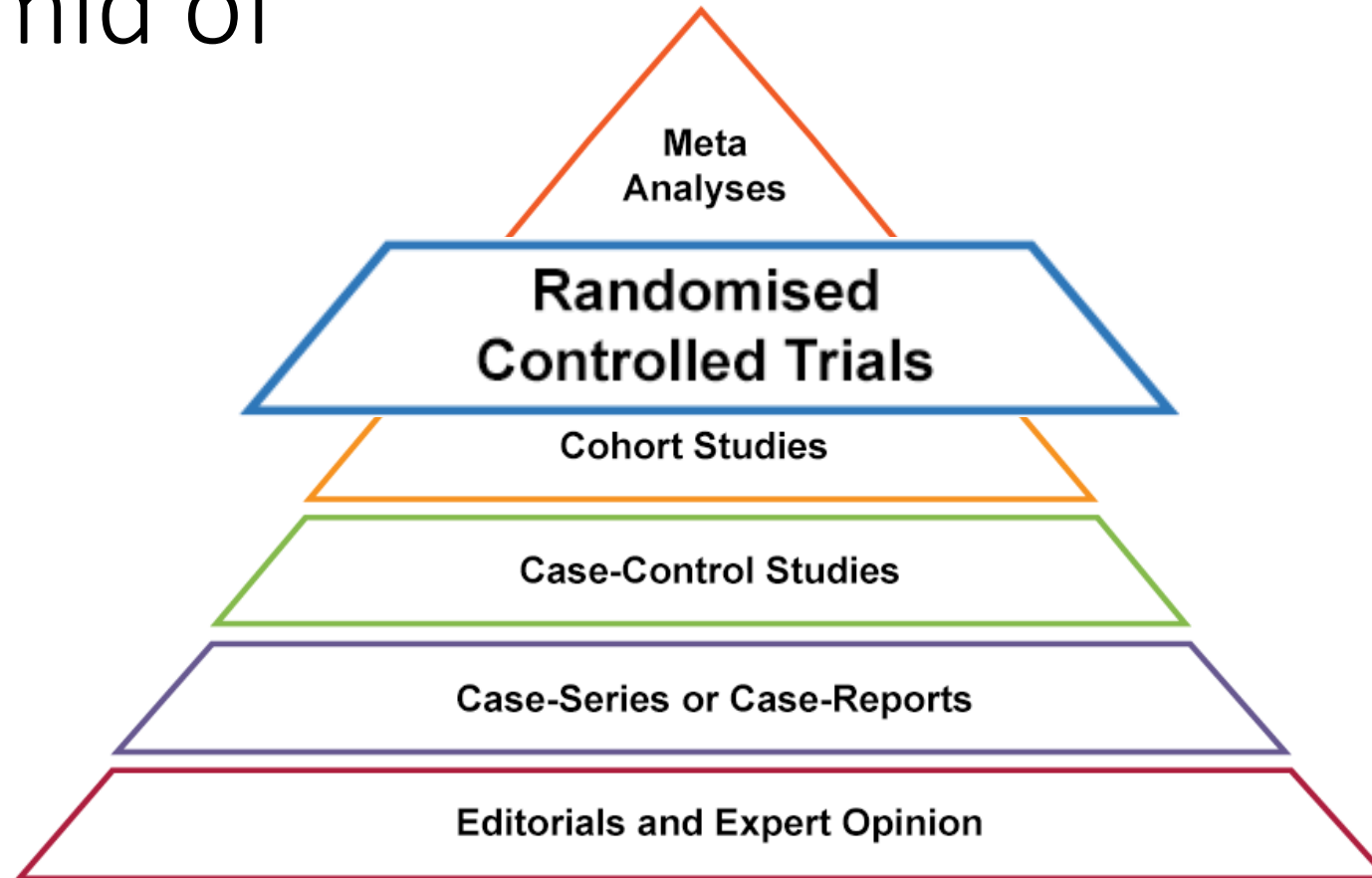
The pyramid of evidence



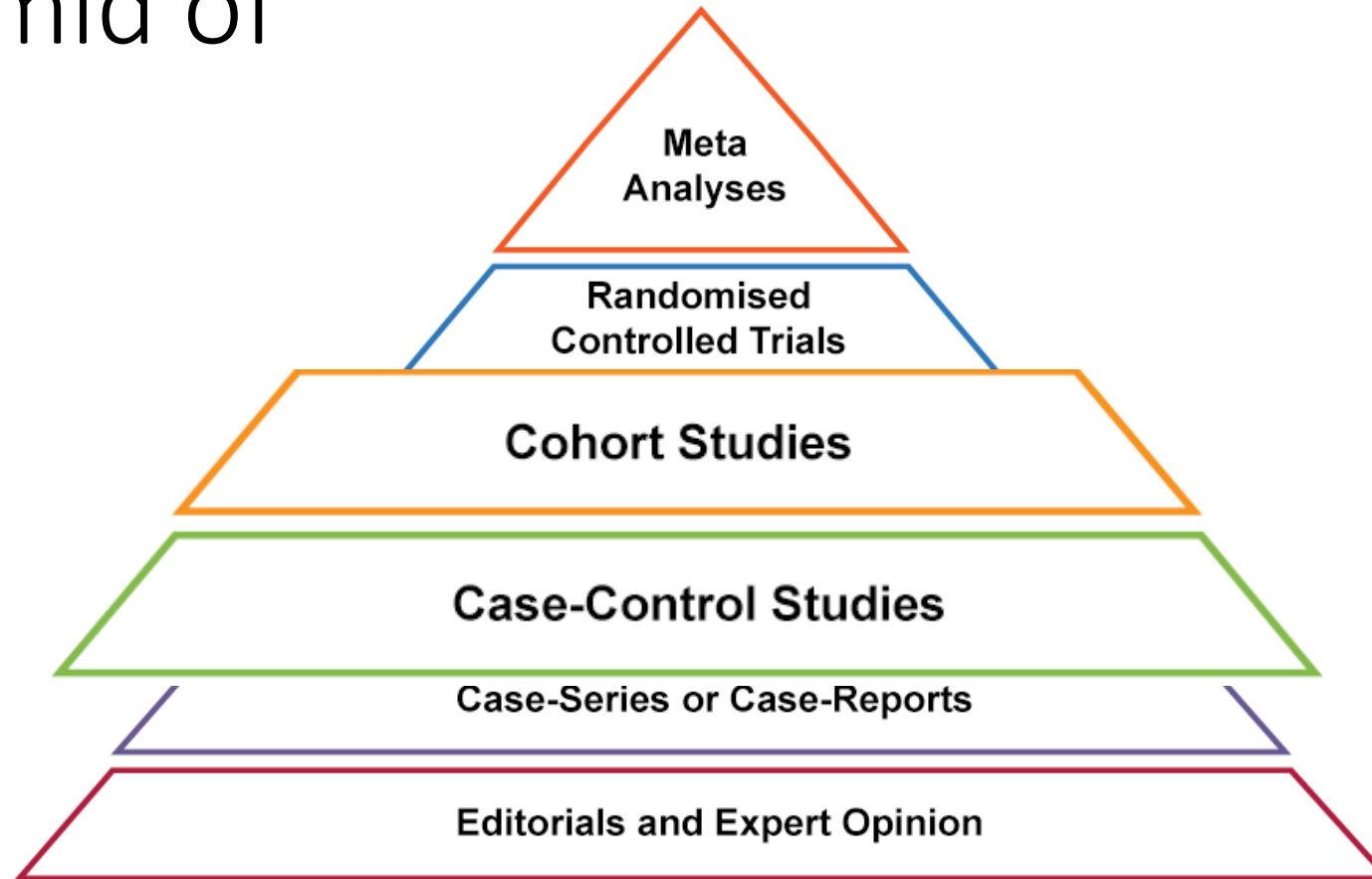
The pyramid of evidence



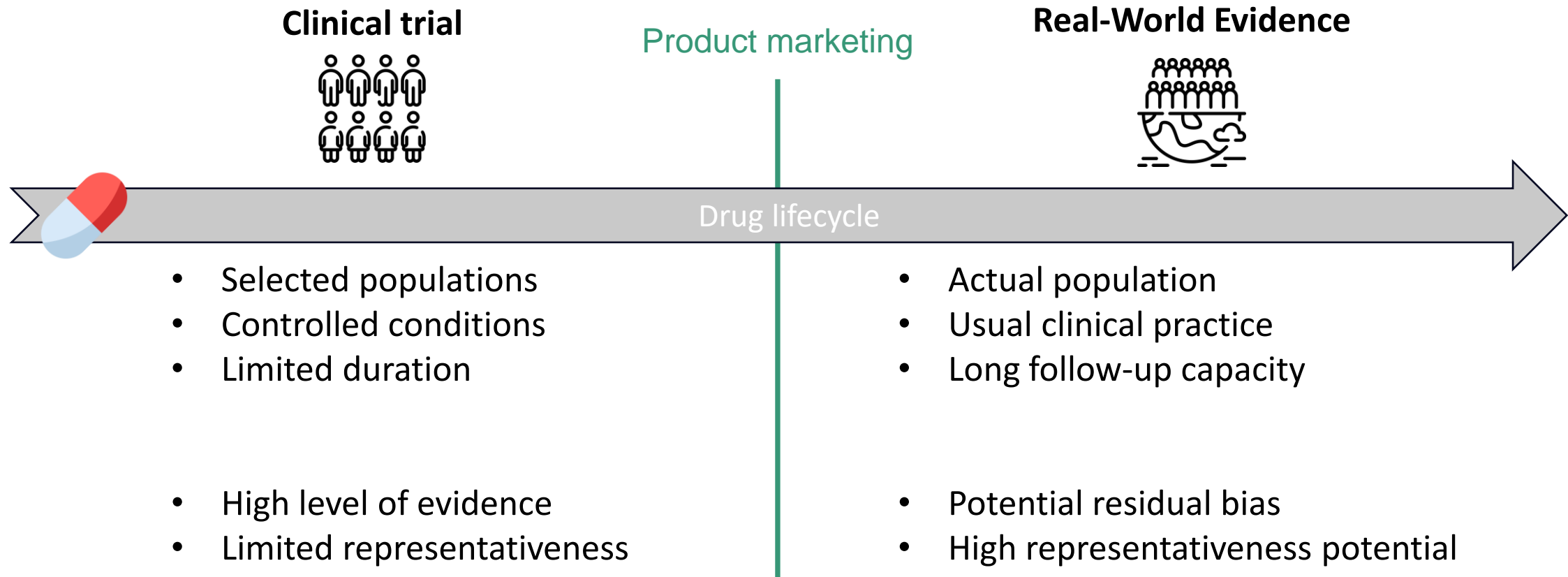
The pyramid of evidence



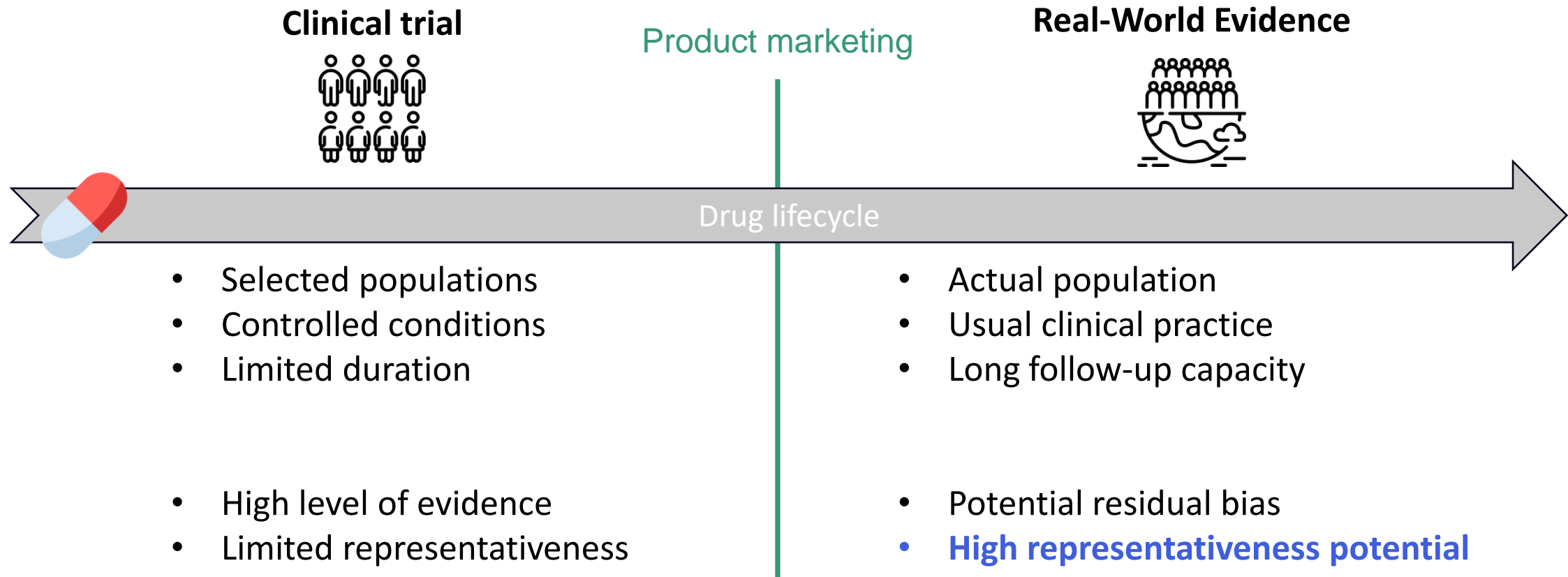
The pyramid of evidence



RWE *versus* Clinical trials



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- Internal validity of the study (limited confounding or potential bias)
- Sufficient sample size
- Good representativeness of the treated population
 - data typology perspective
 - geographical perspective

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=> **Need for multiple sources of real-world data to address a question**

=> **Development of research networks and consortia**



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- Good representativeness of the target population



Exemples



Name of data source	Danish Health Registers		Finnish Health Registers	SNDS	GePaRD	ARS Toscana	Caserta Regional Database	THIN	PHARMO Data Network	Norwegian Health and Administrative Registers	SIDIAP	VID	Swedish Health Registers	Scottish Prescribing Information System	CPRD	
Country	Denmark		Finland	France	Germany	Italy	Italy	Italy	Netherlands	Norway	Spain	Spain	Sweden	UK	UK	
Institution	Aarhus University	SDU	University of Eastern Finland	Bordeaux PharmacoEpi	BIPS GmbH	ARS Toscana	University of Verona	UNIMIB	PHARMO Institute	NIPH	IDIAP JGoI	FISABIO	Karolinska Institute	University of Dundee	RTI Health Solutions	Utrecht University
Type	Linked registers for dispensed prescriptions, laboratory values, hospitalizations, and mortality		Linked national registers for dispensed prescriptions, hospitalisations and outpatient visits, laboratory values, mortality, causes of death	Claims	Claims from 4 SHI providers	Claims	Claims data	Primary health care electronic medical records	Primary health care electronic medical records + partial linkage to other data	Linked national registers for dispensed prescriptions, hospitalizations, specialist outpatient care, primary care, and causes of death	Primary health care electronic medical records + partial linkage to other data	Primary care, specialist outpatient care, hospitalizations, emergency room visits, prescribed and over-the-counter drugs	Linked national registers for dispensed prescriptions, hospitalizations, and mortality.	Prescriptions linked to diagnoses	Primary health care electronic medical records + partial linkage to other data	
Size	5.8 million		5.5 million	66 million	17.5 million	3.6 million	1.2 million	1,7 million full db / 860.000 active patients	4 million	5.5 million	5.6 million	5 million	10.5 million	5.4 million	Aurum: 13.3 million GOLD: 2.9 million of current acceptable patients*	
(% coverage)	(100% Denmark)		(100% Finland)	(99% France)	(21% Germany)	(100% Tuscany)	(21% Campania region)	(1,5% Italy)	(23% Netherlands)	(100% Norway)	(73% Catalonia)	(98% Valencia region, 10.7% Spain)	(100% Sweden)	(100% Scotland)	Aurum: 19.83 % UK, GOLD: 4.4% UK)	
Prescription/ dispensing data	√		√	√	√	√	√	√ (prescription data)	√	√	√	√	√	√	√	√
Hospital data	√		√	√	√	√	√	√ (partial)	√	√	√	√	√	√	√	√
Primary care data			√ (since 2011)		√			√	√	√	√	√				√
Laboratory data	√		√ (since 2014)	√			√ (Lab test request available; around 20% of the lab tests results for people residing in Caserta are performed in public healthcare structures and can be traced)	√ (partial)	√	Only positive tests for notifiable infectious diseases	√	√		√		√
Cancer data	√		√	√	√	√	√	√ (partial)	√	√	√	√	√	√	√	√
Pregnancy data	√		√	√	√	√	√ (pregnant persons can be identified through birth registry - 2018)	√ (partial)	√	√	√	√	√	√	√	√
Emergency data	√		limited	√	√	√	limited, lot of missingness		√	√		√	√	√		√
Disease and procedure coding system(s)	ICD-10		ICD-10 (1996 onwards, data available since 1972s with ICD-8 and ICD-9), procedures NOMESCO	ICD-10	ICD-10-GM for diagnoses; OPS for surgical and diagnostic procedures; EBM for types of treatments and diagnostic procedures	ICD-9-CM; ICD-10-CM	ICD-9	ICD-9-CM; ICD-10-CM	ICD-10	ICD-10 for hospitalisations and specialist care; ICPC-2 for primary care; NOMESCO procedure codes	ICD-10 for primary care diagnoses; ICD-9-CM for hospital discharge diagnoses	ICD-9-CM; ICD-10-ES	ICD-10	ICD-10	SNOMED CT, Read version 2, local EMIS, OPCS-4	
Drug dictionary codes	ATC		ATC	ATC, CIP, EPhMRA	ATC	ATC	ATC and NDC	ATC	ATC	ATC	ATC	ATC	ATC	UK Dictionary of Medicines and Devices (dm+d), ATC	UK Dictionary of Medicines and Devices (dm+d)	
Most relevant publication	Danish HC system publication		Finish HC registers publication	French HC system publication-1	GePaRD publication	Italy HC DBs publication-1	Caserta study publication		PHARMO DB Network publication	Nordic Health Registry-Based Research publication		VID publication	Nordic Health Registry-Based Research publication	PIS publication	CPRD Aurum publication	
				French HC publication-2		From Inception to ConcePTION										

ARS = Agenzia regionale di sanità; CPRD = Clinical Practice Research Datalink; EMR = Electronic medical records; FISABIO = Fundació per al Foment de la Investigació Sanitària i Biomèdica de la Comunitat Valenciana; GePaRD = German Pharmacoepidemiological Research Database; NIPH = Norwegian Institute of Public Health; SDU = Southern Denmark University; SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària; SNDS = French National Healthcare System database; THIN = The Health Improvement Network; UNIMIB = University of Milano Bicocca; VID = The Valencia Health System Integrated Database

Example of federated studies

- COVID related
 - CONSIGN, COVID-19 & Pregnancy (EUPAS39226, EUPAS39438, EUPAS40317)
 - ROC19, Early Covid Vaccines Monitor (EUPAS40404, EUPAS39798)
 - ROC20, Covid Vaccines Monitoring (EUPAS42504, EUPAS39798, EUPAS42467)
 - COVID-19 Vaccine AstraZeneca PASS (EUPAS43593)
 - COVID-19 Vaccine Moderna/Spikevax PASS (EUPAS44424)
 - COVID-19 Vaccine Pfizer-BioNTech/Comirnaty PASS (EUPAS41725)
 - COVID-19 Vaccine Janssen PASS (EUPAS45461)
- **Many other post-authorization safety studies**



Many other examples

<https://catalogues.ema.europa.eu/>

Thank you!

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