Workshop: Evidencias del Mundo Real en la Toma de Decisiones en Salud

ISPOR Latin America

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Mapi
Insight for solutions

Presentador	
Nahila Justo, Mapi Sweden AB y Karolinska Insitute	PRESENTATION OF THE PROJECT AND THE SPEAKERS. BASIC CONCEPTS AND CROSS-COUNTRY COMPARISONS
Sebastián García Marti, Instituto de Efectividad Clínica y Sanitaria (IECS)	REAL WORLD EVIDENCE IN ARGENTINA
Manuel Espinoza Sepúlveda, Pontificia Universidad Católica de Chile	USO DE LA EVIDENCIA DEL MUNDO REAL (RWE) EN LA TOMA DE DECISIONES EN SALUD: EL CASO DE CHILE
Prof. Diego Rosselli, Pontificia Universidad Javeriana de Colombia	REAL WORKS EVIDENCE IN COLOMBIA

Conflicts od Interest Disclosure

- I have provided consultancy services to a number of pharmaceutical companies**. Mapi Group**, the company for which I work, has commercial engagements with them for scientific and consultancy services
- The sponsor of the Latin American Workshops *Use of RWE in Healthcare Decision Making* is **Novartis Pharmaceuticals Corporation**
- The funding for my participation in this conference has been provided to Mapi Group by **Novartis Pharmaceuticals Corporation**

Background and objectives

Why is it so important to count on RWE **as well**?

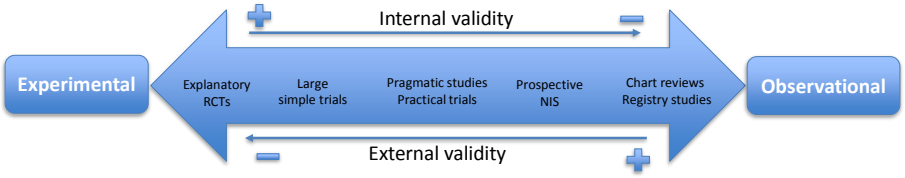
RCTs

- ✓ Restrictive inclusion/exclusion criteria that may lead to selection
- ✓ Controlled design, often blinded and/or vs. placebo
- ✓ Protocol-driven compliance
- ✓ Protocol-driven follow-up
- ✓ Fewer comorbidities and restrictive concomitant medications
- ✓ Reflects ideal financial conditions

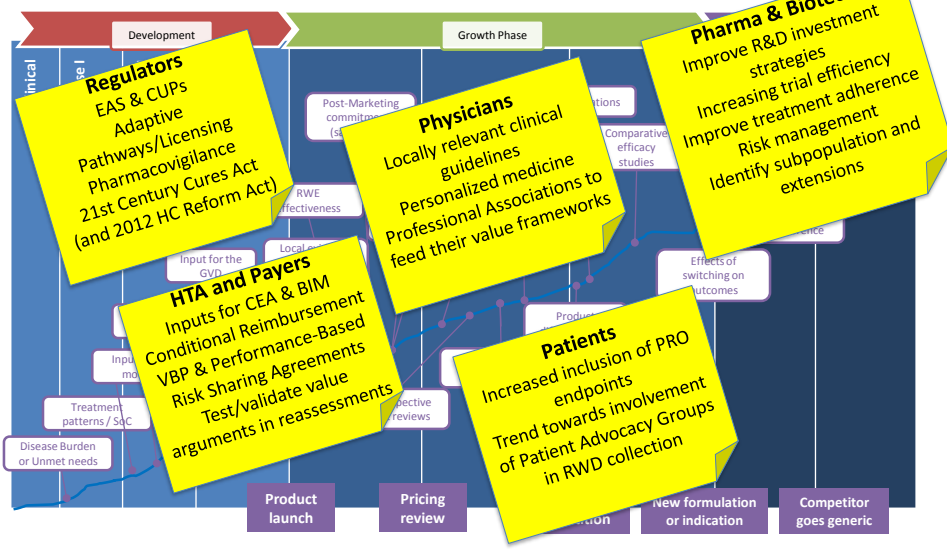
v e r s u s

Reality

- ✓ No restricting inclusion/exclusion criteria
- ✓ Naturalistic open design with real-life comparators
- ✓ Real adherence (patient decision)
- ✓ Real follow-up by physicians discretion
- ✓ All common comorbidities and routine concomitant medications
- ✓ Reflects impact of access problems, copayments, limited coverage, etc.



Uses of RWE



Uses of RWE

No use by regulators

Limited use in HTA (until recently non-binding) → SUR & SUR & Sistema de Tutelaje de Tecnologías Sanitarias Emergentes Limited use in coverage decisions but this is rapidly changing

Main promoter of RWE use are the pharmaceutical industry and academia

No use by regulators

Used in HTAs but results are not always binding

Multiple users (government, insurance, pharma) in price negotiations

Superintendence of Health uses RWE to support auditing

Limited use in HTAs (clinical and economic)

Main promoter is academia

No use by regulators

Used in health decision making, especially pertaining to coverage (DANE)

Multiple national or large scale surveys and national statistics

Challenges

Normative barriers: Difficulties with information security and data integrity

Technical barriers: few databases not regularly updated, non-harmonized codification and no longitudinal follow-up of patients across levels of care

Trust issues and fragmentation

Available RWD not centralized. Fragmented system generate fragmented data

Absence of common indicators' definitions and harmonized coding

Variation in data quality and no longitudinal follow-up of patients' Still insufficient experienced scientist to analyze the data

Hurdles to set SIDRA project

Scarce resources allocated to fund RWE research lack of good quality sources of information in relevant areas

Lack of stewardship of the MoH to drive the production of relevant evidence

The capacity of decision makers, including government, insurers, and health providers, to analyse all this information is limited

Governmental publications do have the descriptive data but no further analyses

Opportinities

The OS will start monitoring the use of certain high-cost technologies (R 370)

Extension of the use of EMRs

Data linked to reimbursement and payment is more detailed and of better quality, especially in the private sector

The vertical integration of insurance companies and healthcare providers create opportunity for complete data repositories.

Some successful initiatives (like Amil in Oncology) have awakened interest

Use in HTA submissions is increasing

Increasing use of RWE in HTAs will promote industry to generate the data

Progressive improvements in data quality

Innovative experiences are improving healthcare provision (and outcomes)

RWE is available from longitudinal data from surveys and registries

Data are freely accessible for any research group interested in further statistical analyses