Experiences and Challenges of using RWE for Decision-Making in Latin America

The George Institute for Global Health UK

Prof. Otavio Berwanger

Executive Director of The George Institute for Global Health UK

Chair in Clinical Trials

Imperial College London

Imperial College London

COI DECLARATION

Research Grants (paid to my institutions)

Astra Zeneca, Bayer, Amgen, Boehringer-Ingelheim, Pfizer, Servier, Novartis

Advisory Boards

Astra Zeneca, Novo Nordisk, Bayer, Amgen, Sanofi, Boehringer-Ingelheim, Servier, Novartis

RWE Applications – Brazil and Latin America

Health Care Systems Research & Quality Improvement

Inform the Design of Implementation Science Studies

REGISTROS BRASILEIROS CARDIOVASCULARES

Brazilian Society of Cardiology- National Registries

Network of over 150 Hospitals

N ~20,000 patients

Accept

Acute Coronary Syndromes (in-hospital)

REACT

Outpatients (high-risk)

RECALL

Patients with Atrial Fibrillation

BREATHE

Patients with Heart Failure (HFrEF)

www.cardiol.br

BRIDGE

Cluster RCT
Myocardial Infaction
34 clusters, 1150 pts
(JAMA 2012)

BRIDGE STROKE

Cluster RCT
Acute Stroke
36 clusters, 1624 pts
(JAMA Neurol 2018)

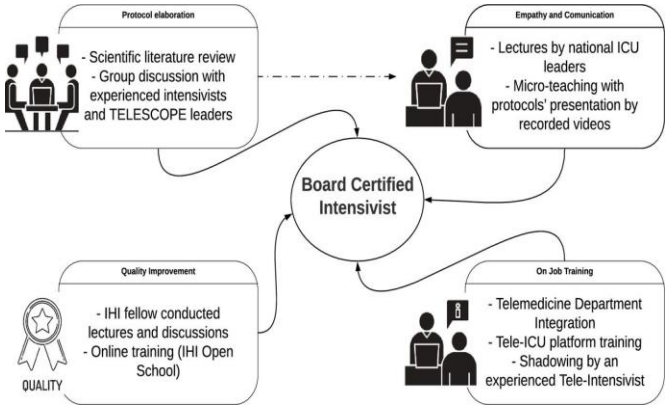
BRIDGE CARDIOVASCULAR PREVENTION

Cluster RCT
CV Prevention
40 clusters, 1619 pts
(JAMA Cardiol 2018)

CHECKLIST ICU Trial

Cluster RCT
ICU Care
118 clusters, 13,638 pts
(JAMA 2016)

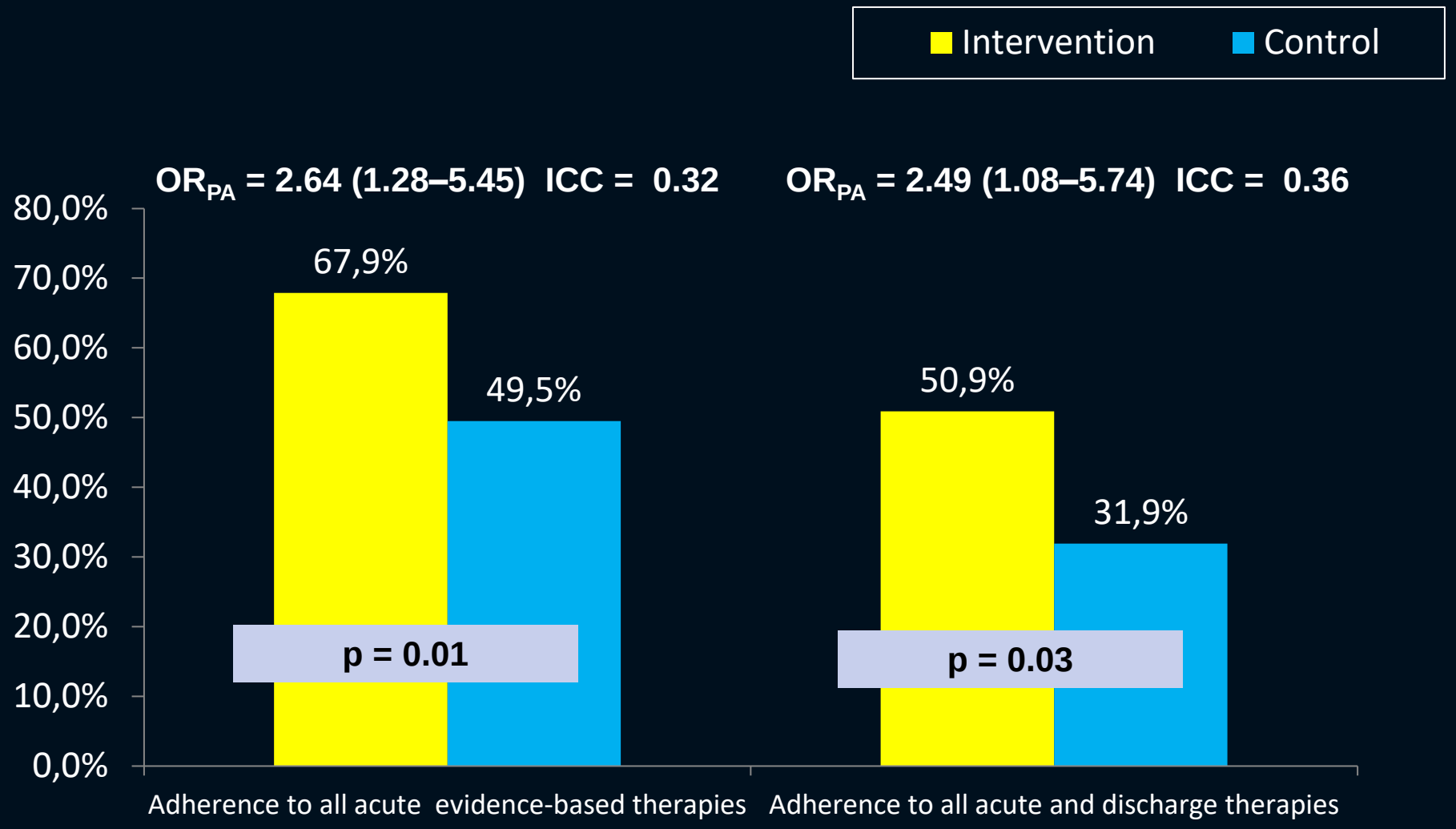
Cluster RCT
Atrial Fibrillation
48 clusters, 2281 pts
(Lancet 2017)



TELESCOPE
Ongoing Cluster RCT
Tele-ICU
30 clusters, 15,000 pts
(Design BMJ Open 2022)

SAPPHIRE-QI
Ongoing Cluster RCT
LDL-C control
30-40 clusters, 3700 pts

Results



Berwanger O et al. JAMA. 2012;307:2041-2049

Large-scale population-based datasets enabled by technology

epSocial

+35k CHW

Our current reach:

4M

people

+4.000 cities

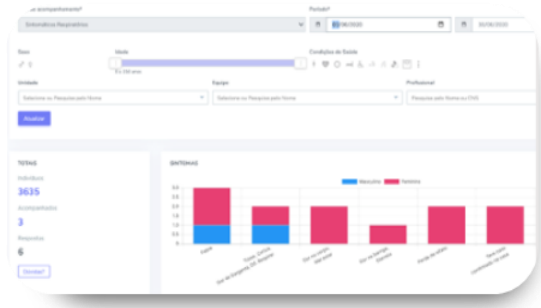
+500k household visits/month

epYou

epPro

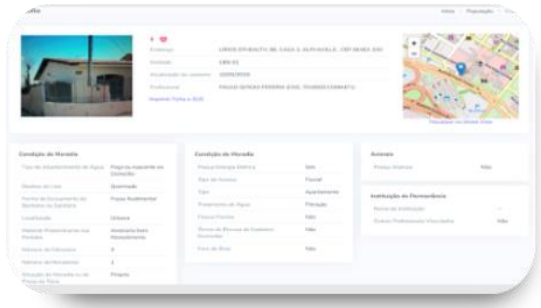
Epidemiological dashboard

epScience



Chronic Diseases

Maps

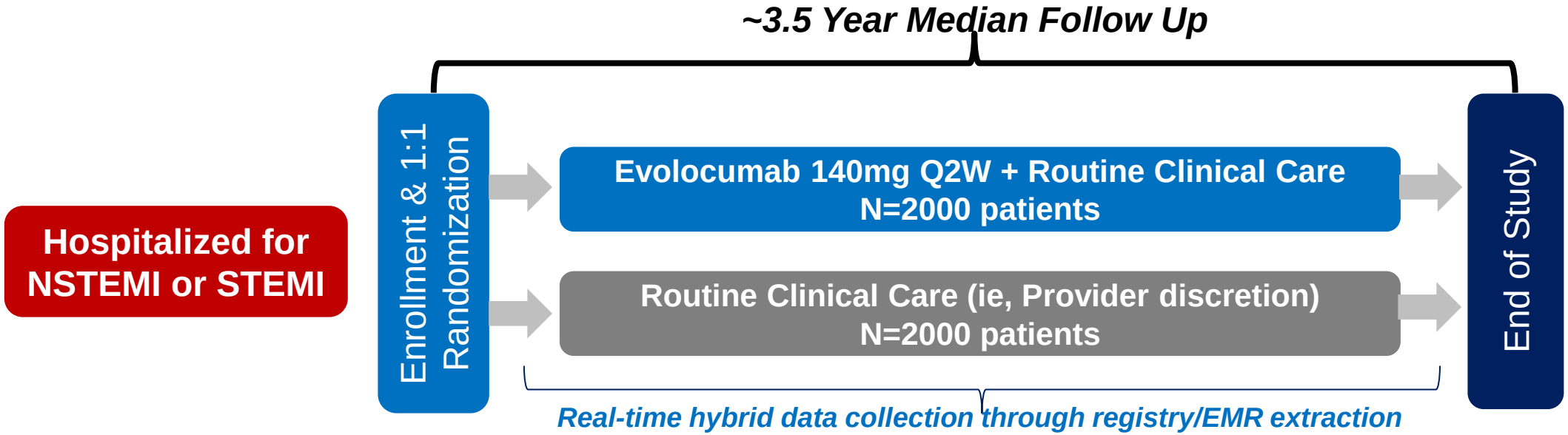


Household

RWE Applications – Brazil and Latin America

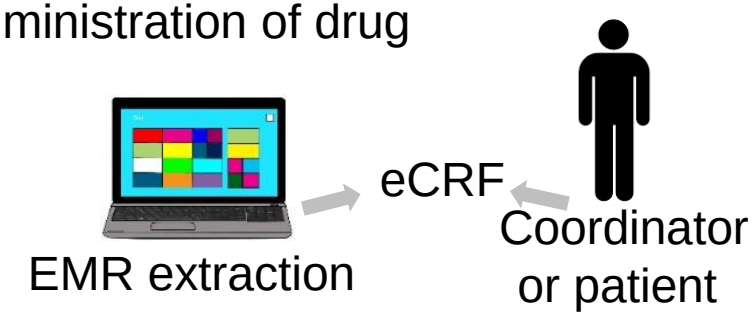
Pragmatic Randomised Clinical Trials using routinely collected data

EVOLVE-MI: EVOLOCUMAB VERY EARLY AFTER MI – STUDY DESIGN



1° endpoint: total (first and subsequent) MI, ischemic stroke, any arterial revascularization, all-cause death

- Evolocumab dosed within 10 days of index MI. Home delivery and self-administration of drug
- ***Pragmatic data collection through EMR, patient- or coordinator-completed eCRF and national registries (in Sweden)***



eCRF electronic case report form, EMR electronic medical record, NSTEMI non-ST elevation myocardial infarction, STEMI ST elevation myocardial infarction

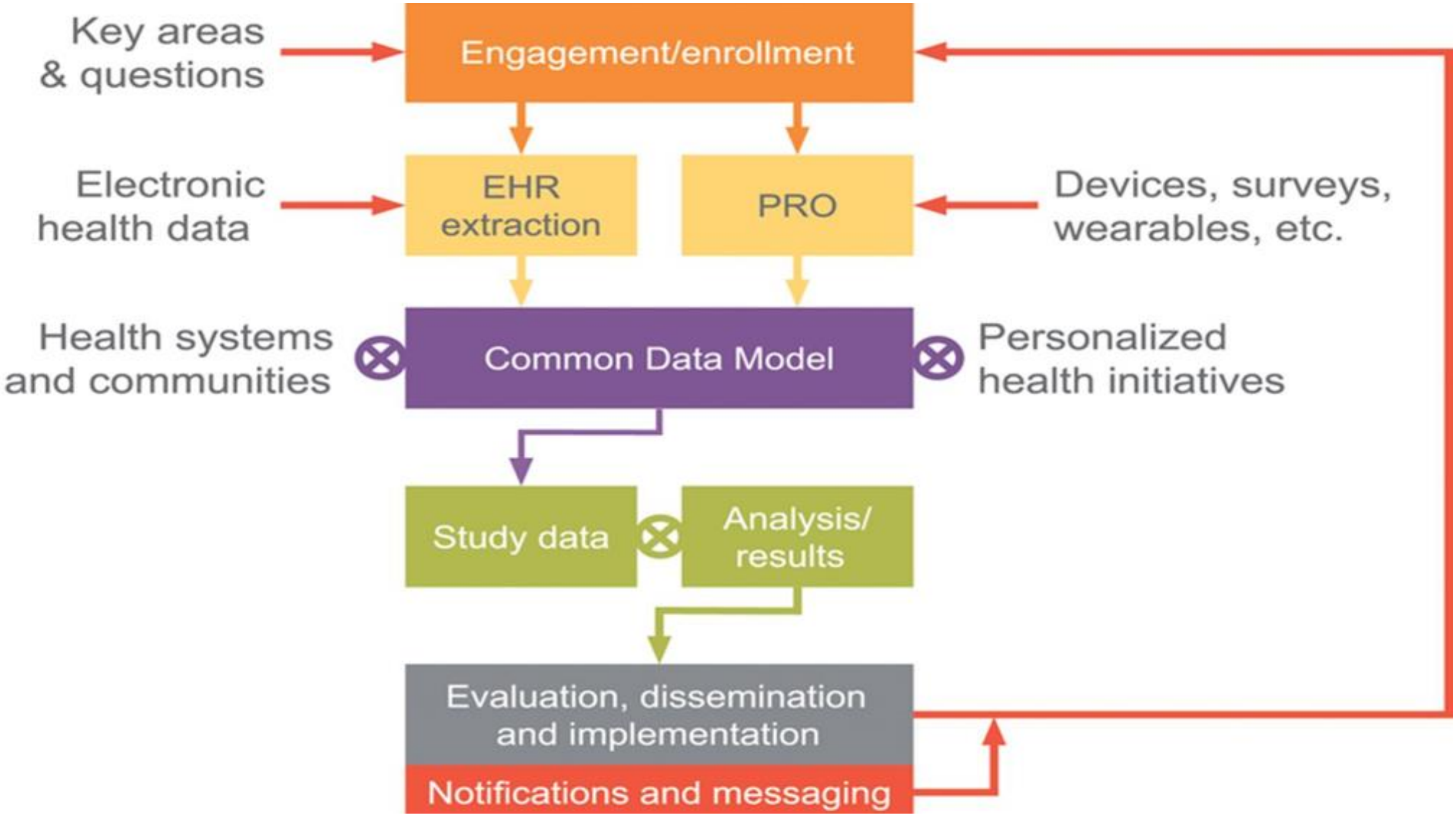
ALBERT EINSTEIN
SOCIEDADE BENEFICENTE ISRAELITA BRASILEIRA

CPC Clinical Research

UCR

Trial Innovations

Traditional Trial	EVOLVE-MI
Manual data entry into eCRF	Hybrid data collection • Passive (e.g., EMR extraction, claims data) • eCRF
Drug dispensed at visits	Study drug delivered to home
Study specific follow-up labs	Labs extracted from EMR
Identification of events via study coordinator	Endpoint collection via EMR, patient surveys, study coordinator
Central event adjudication	Local event review with central adjudication of a subset
Traditional safety reporting (all events, paper forms)	Only AEs / potential endpoints related to study drug, all SAEs, electronic submission


Key areas & questions
Engagement/enrollment
Electronic health data
EHR extraction
PRO
Devices, surveys, wearables, etc.
Health systems and communities
Common Data Model
Personalized health initiatives
Study data
Analysis/ results
Evaluation, dissemination and implementation
Notifications and messaging

RWE Applications – Brazil and Latin America

Outcomes Research

Document Patient care

Latin American Registry of Spinal Muscular Atrophy - RegistrAME

Expected number of patients: around 300
Duration: 24 months

Study design: Observational (retrospective and prospective); non-randomized, international multicenter study- Registration of patients in Latin America (Real World Evidence-RWE).

Setting:
Estimated Number of LATAM centers: 21 centers
Participating countries:
- Argentina
- Brazil
- Chile
- Colombia
- Mexico
- Uruguay

RegistrAME

Target population: Patients with 5q SMA Types 1, 2, 3 and 4 (with or without DMTs (without disease-modifying treatment)).

Inclusion criteria:
- Genetically confirmed 5q SMA patients at all ages;
- Consent to participate in the study, expressed by the patient or responsible or legal guardian of the pediatric patient/ responsible or legal guardian of the patient with cognitive impairment of understanding the registration protocol.

Exclusion criteria:
- Patients without a genetic diagnosis confirming 5q SMA;
- Other types of SMA (non 5q SMA);
- Patients who do not accept to participate in the observational study;
- Patients without the legal capacity who are unable to understand the nature, significance and consequences of participating in the registry, or, in such cases, without a legal or responsible guardian.

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