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SCIENCE MEDICINES HEALTH

A Regulator's view on:

Could real world evidence data become the co-driver of regulatory and reimbursement decisions?

Panel discussion for: Can "Real World Evidence Data" advance equity of health care in Europe?

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The views expressed in this presentation are my personal views and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

What is real world data?

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Real world evidence is defined as data that are collected outside the constraints of conventional randomised clinical trials.

Registries

Electronic Health Records

Digital phenotypes

Hospital data

Patient and physician surveys

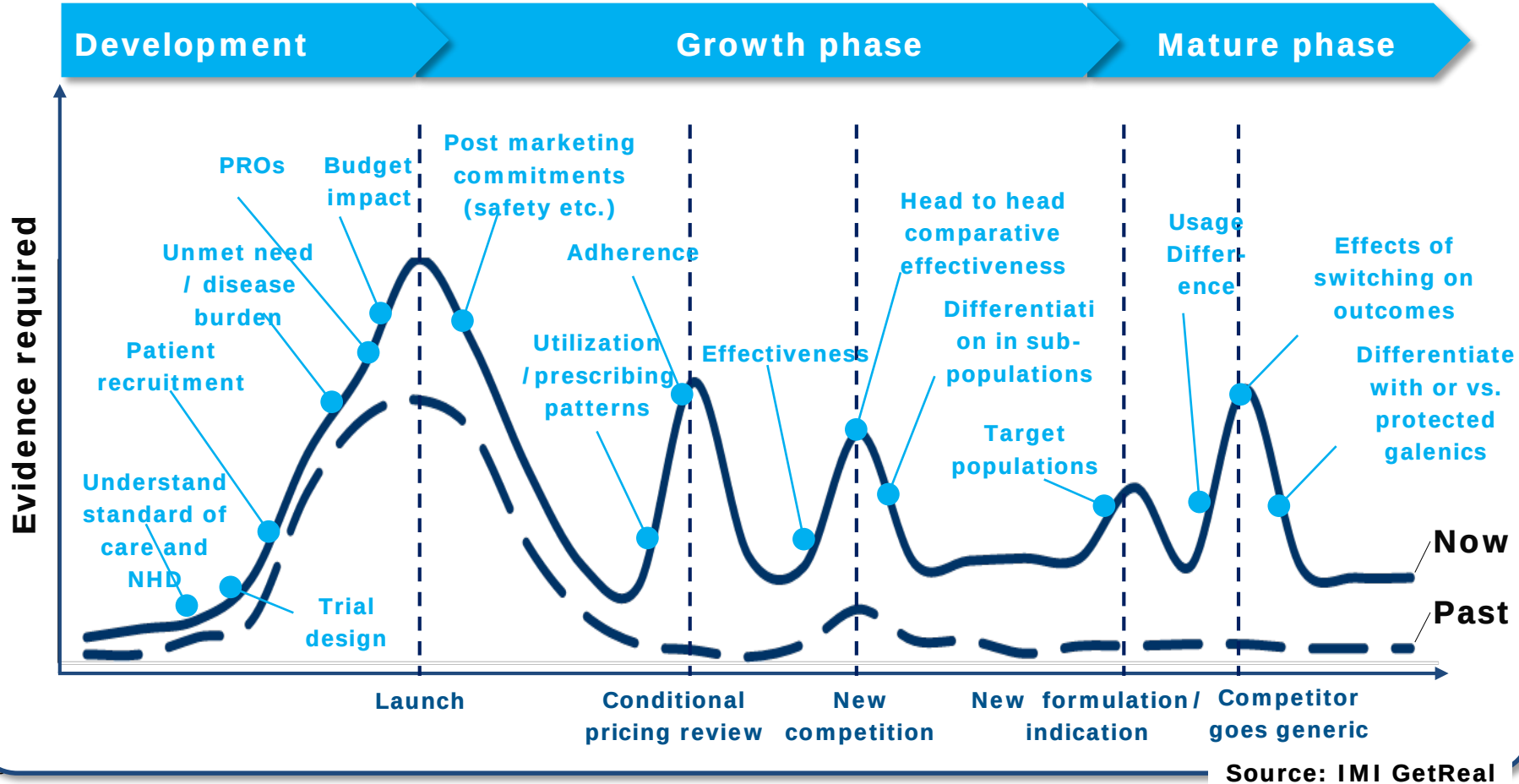
Health Insurance Data

Genomes

Biobanks

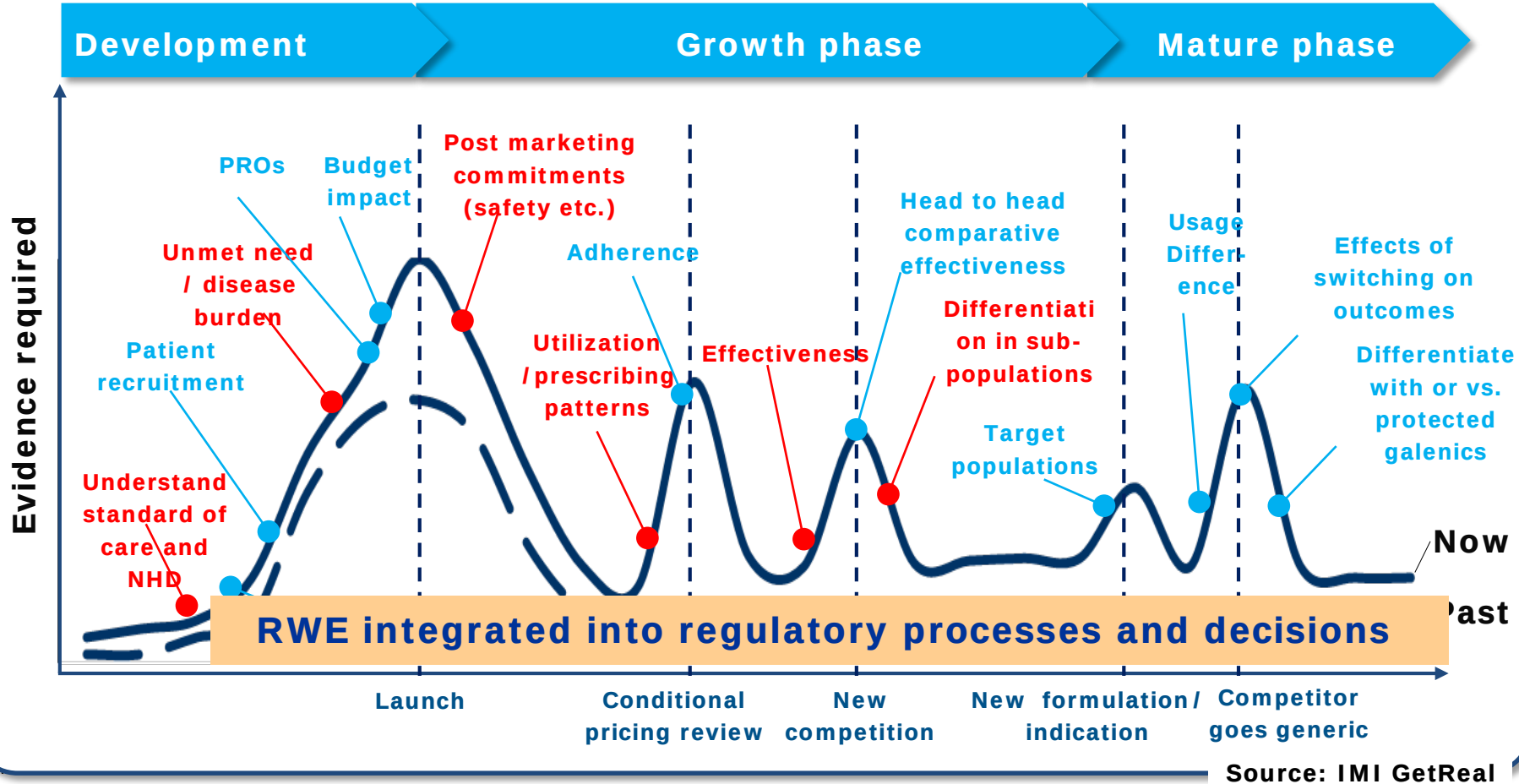
Social media

Business Case – RWE in the product life cycle



Source: IMI GetReal

Business Case – RWE in the product life cycle



Source: IMI GetReal

Use of real-world data in regulatory decision-making

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What is the relevant patient population for gene therapy?

What is the incidence and outcome of opportunistic infections with natlizumab?

What is compliance in the elderly?

Genetic basis of responder/non responder status

What are the long term health benefits of a new treatment compared with standard treatment?

What was the impact of the regulatory action following the Article 31 Referral on Combined hormonal contraceptives on prescribing and VTEs?

What is the risk of bleeding in new users of DOACs compared with warfarin?

Genetic susceptibility to adverse drug reactions

Patterns of codeine prescribing across Europe and the incidence of death

Infection spread following vaccination

What is the extent of off label prescribing with SGLT2 inhibitors?

Benefits of access to and use of real world evidence

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1 Improving medicines development

- Enabling innovation
- Understand the disease and target population
- Understand treatment outcomes
- Better evidence supplementing Clinical Trials

2 Post-authorisation

- Utilisation and prescribing patterns
- Faster identification and assessment of safety issues
- Effectiveness data
- Determining safety and efficacy in high risk groups

3 Overarching benefit

- Improved EMA and HTA decision making
- Optimising use of medicines through ongoing monitoring
- Ability to define the impact of regulatory / HTA decisions

EMA, will undertake to improve stakeholder collaboration and make better use of registries through:

- mechanisms for regulators and marketing authorisation applicants *to systematically consider the need for registries and interact with registry holders*;
- *sharing and disseminating information* on disease registries;
- recommending *governance principles and standards* for stakeholder interactions;
- making recommendations on *core data elements and quality standards* acceptable for regulatory and HTA decision-making;
- identifying *registry holders' needs for methodological and technical guidance*;
- investigating what *patient-reported outcomes* registries should collect;
- exploring further measures to improve the *sustainability of registries*.

Thank you