The GetReal Project

Aim

To develop a common understanding of the **acceptability and usefulness** of innovative development programmes which use **real-world evidence (RWE)** to estimate the effectiveness of new medicines
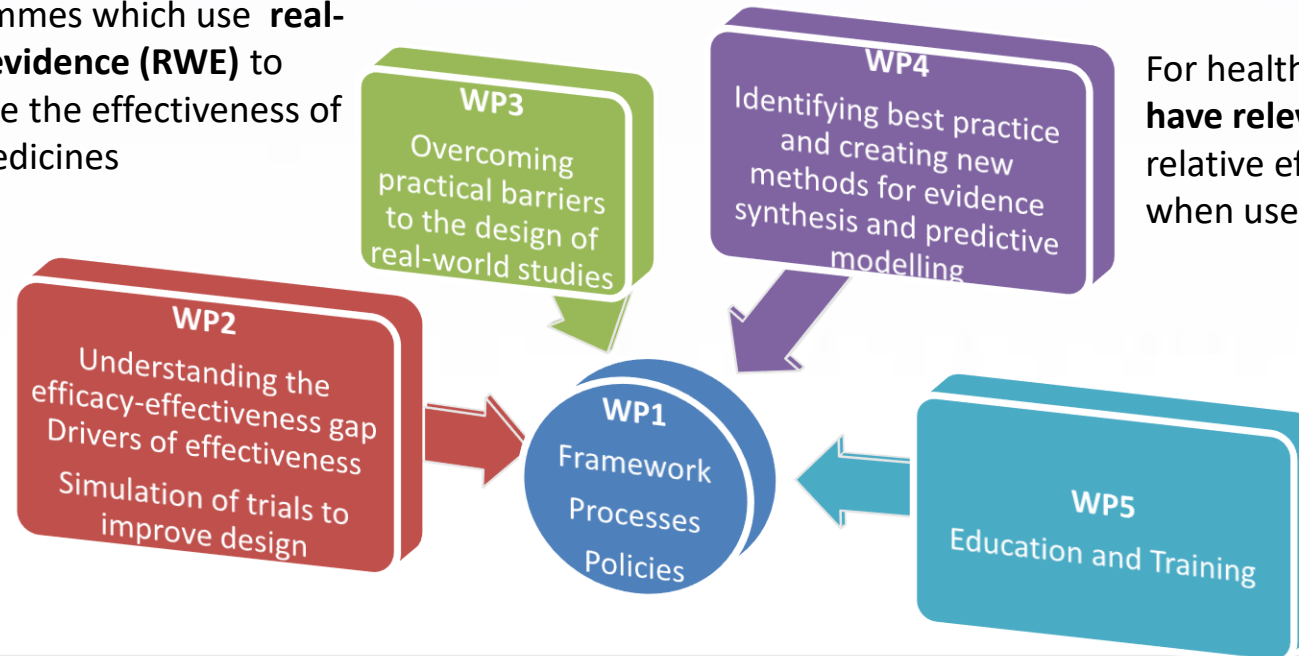
Focus

Use of RWE in an **early setting,** prior to marketing authorisation or reimbursement

Overall vision

To provide pharma R&D with guidance on the most appropriate ways for developing **evidence of relative effectiveness**
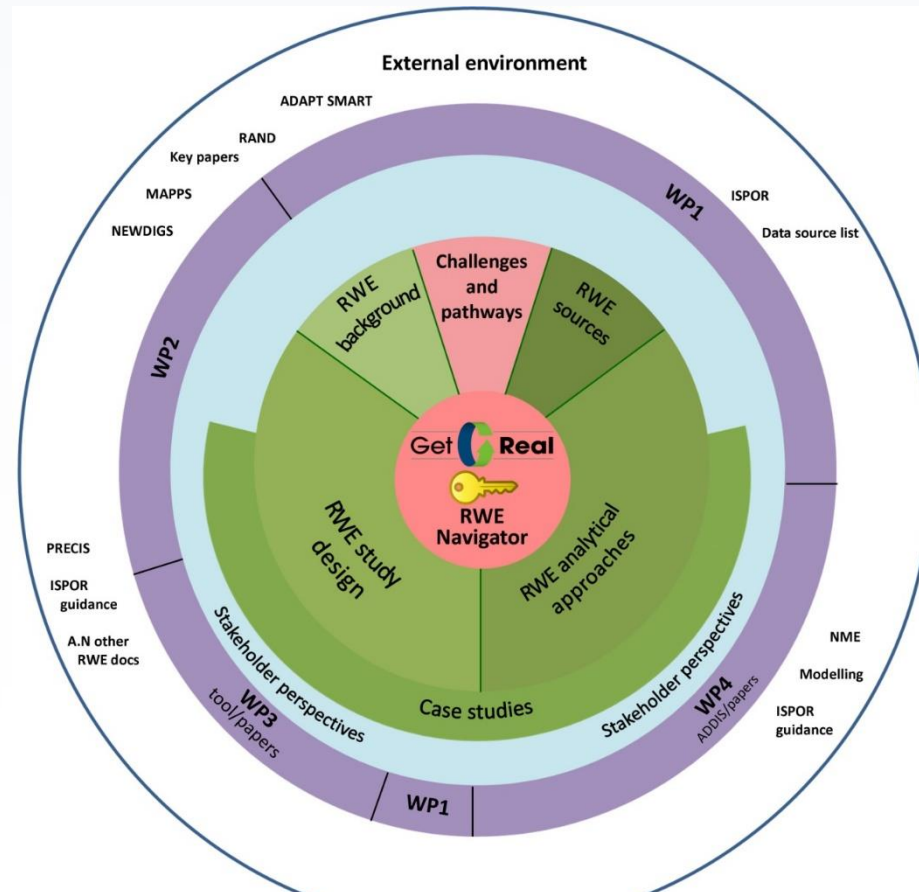
For healthcare decision makers to **have relevant evidence** to assess relative effectiveness of new drugs when used in standard practice

WP3
Overcoming practical barriers to the design of real-world studies

WP4
Identifying best practice and creating new methods for evidence synthesis and predictive modelling

WP2
Understanding the efficacy-effectiveness gap
Drivers of effectiveness
Simulation of trials to improve design

WP1
Framework
Processes
Policies

WP5
Education and Training

- **Platform for collaboration**
- EU and US representatives from HTA, regulators, EFPIA partners and academia, patients and clinicians

- **Development of the RWE Navigator:**
- an interactive tool to walk stakeholders through defining evidence gaps and study approach and design option https://rwe-navigator.eu

- **Development of policy recommendations**
- Advancing Evidence Generation for New Drugs: IMI GetReal's Recommendations on Real-World Evidence

Primary stakeholders: Pharma R&D, Regulatory, HTA
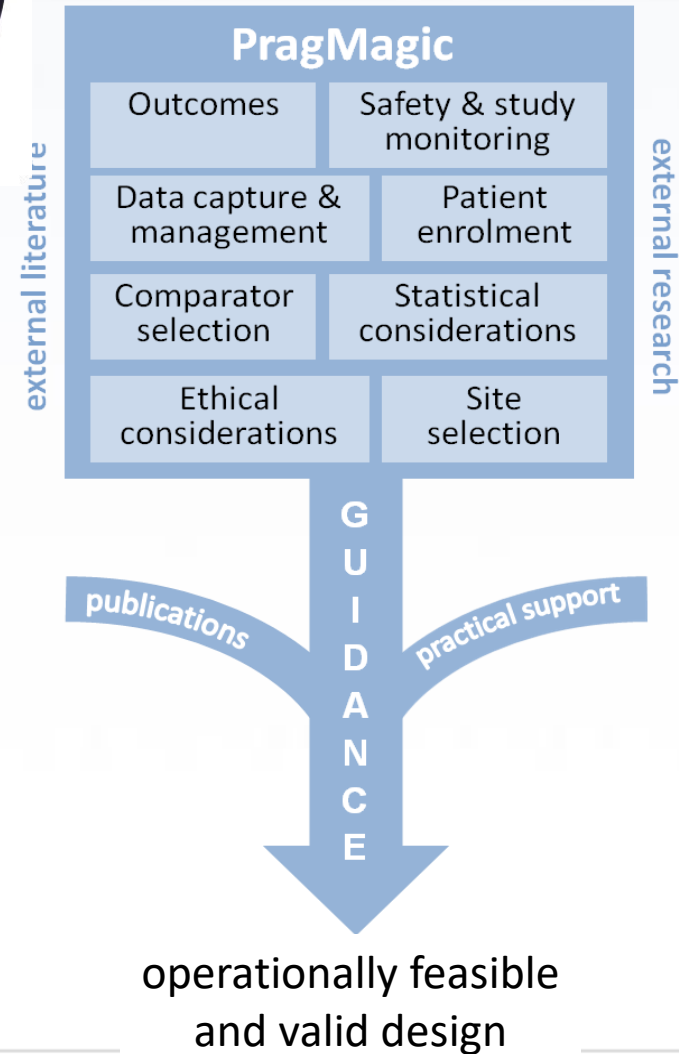
All phases of drug development

PragMagic

Web-based tool interactively guiding study teams through various design choices to:

→ create awareness on likely practical challenges, their impact and possible solutions

→ understand the impact of choices on the operational feasibility of trial execution, generalizability, validity and precision of trial results

PragMagic

external literature	PragMagic		external research
	Outcomes	Safety & study monitoring	
	Data capture & management	Patient enrolment	
	Comparator selection	Statistical considerations	
	Ethical considerations	Site selection	

publications **GUIDANCE** practical support

operationally feasible and valid design

We need to build on the success of GetReal

RWE Navigator

Tool Kit

ADDIS

Education & Training

Framework for stakeholder engagement

Innovative Methodologies

PRAGMAGIC

Publications & White Papers

Policy Recommendations

✓ We've built the trust to enable stakeholders to collaborate

✓ Together we've built tools to facilitate the generation of high quality RWE and support our stakeholders with the interpretation of RWE

✗ But without increasing confidence in the use of RWD in decision making our tools will lack long-term impact: que the **IMI-GetReal Initiative!**