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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.

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking GetReal Initiative grant no. 807012.
Key Achievements

- **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](https://rwe-navigator.eu)

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

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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

operationally feasible and valid design
We need to build on the success of GetReal

- RWE Navigator
- Tool Kit
- ADDIS
- Education & Training
- 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!