The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking under grant agreement no [115303], resources of which are composed of financial contribution from the European Union’s Seventh Framework Programme (FP7/2007-2013) and EFPIA companies’ in-kind contribution.

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The GetReal Project

Professor Sarah Garner
Associate Director R&D NICE
On behalf of the GetReal consortium

- **Innovative Medicines Initiative (IMI)**
  - Europe’s largest public-private initiative
  - joint undertaking between European Union and European pharmaceutical industry association EFPIA.

- **GetReal**
  - Understanding how real-world data can contribute to decision-making
    - October 2013 to December 2016 (39 months)
    - 29 partners
    - Total budget: €18 million
      - 50% staff from the 15 participating pharma companies
      - 50% cash contribution from the EU to fund ‘public’ sector
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Universities, research organisations, public bodies, non-profit groups
- Universitair Medisch Centrum Utrecht, the Netherlands
- Academisch Ziekenhuis Groningen, the Netherlands
- Zorginstituut Nederland, the Netherlands
- European Medicines Agency, UK
- European Organisation for Research and Treatment of Cancer, Belgium
- Haute Autorité de Santé, France
- London School of Hygiene and Tropical Medicine, UK
- National Institute for Health and Care Excellence, UK
- Panepistimio Ioanninon, Greece
- Universität Bern, Switzerland
- University of Leicester, UK

Small and medium-sized enterprises (SMEs)
- LA Santé Epidemioleogie Evaluation et Recherche, France

Patients’ organisations
- International Alliance of Patients’ Organizations, UK

EFPIA companies
- GlaxoSmithKline Research and Development Ltd, UK
- Amgen NV/SA, Belgium
- AstraZeneca AB, Sweden
- Bayer Pharma AG, Germany
- Boehringer Ingelheim International GmbH, Germany
- Bristol Myers Squibb EMEA sarl, US
- Eli Lilly, UK
- F. Hoffmann-La Roche AG, Switzerland
- Janssen Pharmaceutica NV, Belgium
- Merck KGaA, Germany
- Merck Sharp & Dohme Corp., US
- Novartis Pharma AG, Switzerland
- Novo Nordisk A/S, Denmark
- Sanofi-Aventis Research and Development, France
- Takeda Development Centre Europe Ltd, UK

WP1 Frameworks Processes Policies
- Standardising terminology
- Interviews to understand and the perspectives and policies of different stakeholders
- Designing a framework for decision-making during development

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

WP3 Overcoming practical barriers to the design of real-world studies
- 5 Case studies using drugs that had difficulty at regulation and HTA
  - 360 degree reviews
  - Re-designing development pathways to include real-world data
  - Simulation
  - Ascertaining impact on decision makers

WP4 Identifying best practice and creating new methods for evidence synthesis and predictive modelling
**WP1: Testing out different strategies and pathways**

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Evidence Generation</th>
<th>Evidence Synthesis</th>
<th>Reg/reimb decision making</th>
<th>Impact</th>
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<tr>
<td>Actual</td>
<td>TRIALS A AND B</td>
<td>Pivotal</td>
<td>EMA: Dossier NICE: C-U</td>
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<td>Alternative1</td>
<td>AMEND TRIAL B</td>
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<td>As Actual</td>
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<td>Timescale ↔ Acceptability ↓</td>
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<tr>
<td>Alternative2</td>
<td>As Actual</td>
<td>INTRODUCE NMA (+ RWE)</td>
<td>As Actual</td>
<td>Costs ↔ Uncertainty ↓↓</td>
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<td>INTRODUCE NMA (+ RWE)</td>
<td>Control Arms of RCTs + Registry</td>
<td>Costs ↔ Uncertainty ?↓</td>
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<td>Timescale ?↔ Acceptability ?</td>
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Source: GetReal WP1 Keith Abrams

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**Closing remarks**

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Hierarchies of evidence should be replaced by accepting—indeed embracing—a diversity of approaches.

This is not a plea to abandon RCTs and replace them with observational studies. Nor is it a claim that the bayesian approaches to the design and analysis of experimental and non-experimental data should supplant all other statistical methods.

Rather, it is a plea to investigators to continue to develop and improve their methods; to decision makers to avoid adopting entrenched positions about the nature of evidence; and for both to accept that the interpretation of evidence requires judgment.