



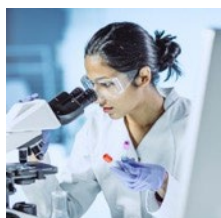
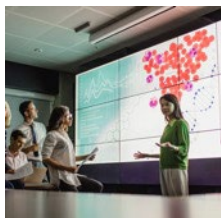
European Federation of Pharmaceutical  
Industries and Associations



# Reflections on EMA data workplan: learnings and priorities for the future

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Fifth EMA/HMA Big Data  
Stakeholder Forum



# Learnings from last few years through BDSG workplan<sup>1,2</sup>

	Advancements	Examples	To be enhanced/improved
1	<b><u>More structured approaches and resources</u></b> to use data and evidence for decision making	DARWIN EU, RWD/Studies Catalogues	Further build <b>trust and transparency</b> on how data and evidence is generated <b>fit-for-purposely (FFP)</b> and used in <b>decision-making</b> . (e.g. feasibility assessment, HTA requested studies)
2	<b><u>Enhanced capability and guidances</u></b> in data quality, methodologies, governance	Data Quality Framework, Raw Data pilots, AI reflection paper	Further guidances on <b>Data Quality (DQ)</b> and considerations in specific areas (e.g. RWD incl. Registries, Pharmacovigilance, etc.).
3	<b><u>International harmonisation efforts</u></b> on RWE	ICH RWE Reflection Paper, ICMRA collaboration on RWE	Further optimisation of <b>streamlined processes and harmonised approaches</b> globally ( <b>Harmonisation</b> ). <ul style="list-style-type: none"> <li>timely progress and updates of ICH RWE topics listed in the ICH RP<sup>3</sup></li> <li>further collaboration and updates of ICMRA progress on RWE activities<sup>4</sup></li> </ul>
4	<b><u>Strengthened collaborations</u></b> with a broad range of stakeholders	<b>Big data multi-stakeholder forums</b> – RWE, Registries, Methodologies, AI; <b>EMA-industry</b> stakeholder meetings and RWE focus group; <b>EMA-HTA workshop</b> on RWE and DARWIN EU	<ul style="list-style-type: none"> <li>Further <b>partnerships across stakeholders</b> to advance methodologies and share insights.</li> <li>Further transparency of <b>HTA use cases</b> in DARWIN EU</li> </ul>

1. [EMA \(Jun 2024\) BD workplan 2022-2025 v1.4](#); 2. [EMA \(Jan 2024\) BDSG 2023 report](#);  
3. [EMA \(July 2024\) ICH reflection paper on RWE](#); 4. [Beck et al \(Oct 2024\) Collaborative RWE among regulators - ICMRA COVID-19 Real-World Evidence \(RWE\) and Observational Studies Working Group](#)

# Expected trends in data in medicines next few years

1. **Artificial Intelligence (AI):** Advanced methodology and tools (digital) for data generation and analytics
2. **Patient centricity:** Patient engagement, experience, patient-relevant & meaningful endpoints, novel approaches in patients' data generation (e.g. point-at-care data collection)
3. **Collaboration and coordination:** intensified centralised coordinated approaches towards data and evidence requirements across medicines life-cycle, for example:
  - **Regulatory** (e.g. international, regional, national coordination: **EHDS, ICH, ICMRA**),
  - **HTA** (e.g. pan-EU centralisation: **EU HTA Regulation**),
  - **Cross-sector** integrated data generation and use (e.g. patients, HCPs, academia, industry, etc.),
  - **Data quality requirements** converging/overlapping considerations in relevance and reliability (e.g. RWD, AI data)

# Future priorities based on learnings and expected trends

## Future Priorities

1. **Guidances** for how **RWE is considered and accepted in regulatory decision making** (e.g. share feasibility assessments, how HTA requested studies via DARWIN EU is used for decision-making), ensuring transparency, trust, fit-for-purpose, and predictability in RWE generation and application.
2. **Guidances (Q&As)** on **practical considerations** in tools, systems, issues in implementation of frameworks and principles: RWD (incl. registries), PV, etc.
3. **Guidances** on how **patients' inputs, data and evidence** are to be considered and used in regulatory decision making.
4. **Dedicated channels and focused approaches** to discuss and collaborate on specific topics with stakeholder groups: e.g. AI, digital tools/mHealth, Data Quality, etc.
5. **Shared learning forums** for cross-sector exchanges in best practices, advanced methodology, innovations, etc.

### Learnings

FFP, DQ,  
Harmonisation  
/Partnership



### Expected Trends

AI, Patients,  
Centralisation