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[1,2]

	Advancements	Examples	To be enhanced/improved
1	**More structured approaches and resources** to use data and evidence for decision making	DARWIN EU, RWD/Studies Catalogues	Further build **trust and transparency** on how data and evidence is generated **fit-for-purposely (FFP)** and used in **decision-making**. (e.g. feasibility assessment, HTA requested studies)
2	**Enhanced capability and guidances** in data quality, methodologies, governance	Data Quality Framework, Raw Data pilots, AI reflection paper	Further guidances on **Data Quality (DQ)** and considerations in specific areas (e.g. RWD incl. Registries, Pharmacovigilance, etc.).
3	**International harmonisation efforts** on RWE	**ICH** RWE Reflection Paper, **ICMRA** collaboration on RWE	Further optimisation of **streamlined processes and harmonised approaches** globally **(Harmonisation)**. • timely progress and updates of ICH RWE topics listed in the ICH RP[3] • further collaboration and updates of ICMRA progress on RWE activities[4]
4	**Strengthened collaborations** with a broad range of stakeholders	**Big data multi-stakeholder forums** – RWE, Registries, Methodologies, AI; **EMA-industry** stakeholder meetings and RWE focus group; **EMA-HTA workshop** on RWE and DARWIN EU	• Further **partnerships across stakeholders** to advance methodologies and share insights. • Further transparency of **HTA use cases** in DARWIN EU

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

Learnings

FFP, DQ, Harmonisation /Partnership

+

Expected Trends

AI, Patients, Centralisation

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.