# Stakeholder Actions Implementation Form

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* *Mandatory fields*

## 1. Contact Information

**Full Name:**

***Organisation:**

***Email:**

***Country:**

## 2. Select the Stakeholder Actions relevant to your project

***Question 1: Which of the Stakeholder Actions does your story best align with?**

*(Select all that apply)*

**HTA/Payer Bodies**

☐ 1.1 Shared vision on use of RWD

☐ 1.2 Overcome fragmentation and lack of collaboration

☐ 1.3 Collaborate via HTA/Payer networks to align PLEG requirements ☐ 1.4 Engage with companies on RWE generation plans

☐ 1.5 Influence the development of national secondary use governance frameworks ☐ 1.6 Require feasibility assessments, study protocols, etc. to be made public

□ 1.7 Share case studies on RWE influence over P&R and reassessments

### Payer/HTA Collaborations

□ 2.1 Leverage regional collaborations for coordinated use of RWD in decision-making □ 2.2 Develop joint voice on RWD issues to feed into EU-level policy issues

□ 2.3 Co-create RWD/E learning platforms with other stakeholders

□ 2.4 Work with regulators to align on RWD/E methods and guidance

□ 2.5 Provide early scientific advice on RWE generation over the product lifecycle

□ 2.6 Support industry in expanding post-authorisation studies to also address HTA/Payer needs

□ 2.7 Promote open access to findings to design a shared understanding of HTA requirements with other stakeholders

□ 2.8 Co-design and streamline shared frameworks for data quality assessment and standardisation with regulators

□ 2.9 Pilot the use of RWD/E methods guidance in assessment and share learnings

□ 2.10 Co-develop harmonised RWE guidance with academia and industry to support HTA Regulation implementation

□ 2.11 Build a portal of publicly available examples of post-launch RWD collection and RWE generation requirements

### Pharmaceutical Industry

□ 3.1 Engage with HTA/Payers throughout the product lifecycle on integrating RWE into evidence generation plans

□ 3.2 Ensure transparency in pivotal RWE study design, execution and analysis

□ 3.3 Vertically and horizontally integrate in-house knowledge to map national/regional HTA & Payer RWE needs

□ 3.4 Cooperate on RWD transportability alignment across borders

□ 3.5 Drive multi-stakeholder discussions about OBMEA and PLEG alignment □ 3.6 Digitise the collection of patient-relevant outcomes

□ 3.7 Collaboratively explore with other developers synergies in RWD collection and analysis

□ 3.8 Ensure data quality and interoperability through early engagement with clinical networks and registries

□ 3.9 Support the implementation of the EU HTA Regulation by advocating for clear guidance on RWE in JCA dossiers

□ 3.10 Enable exchanges of best practices and learnings from submissions of RWE to HTA or post-launch evidence requirements

### Clinical

□ 4.1 Support the European Health Data Space to raise awareness about the value of secondary use of health data

□ 4.2 Involve patients and collaborate with other clinical networks, regulators and HTA/Payer bodies in the development of fit-for-purpose data collection systems for patient-relevant outcomes

□ 4.3 Support educating medical practitioners and hospital staff on the importance of health data collection and use

□ 4.4 Advise health systems on the most efficient and high-quality collection of RWD by clinical teams

□ 4.5 Involve clinical teams and patients in the design of data collection systems and governance structures

□ 4.6 Ensure patient-centricity in local information governance systems for informed consent-based processes

**Patient Groups**

□ 5.1 Empower patients' role in RWE generation for informed HTA and policy decision- making

□ 5.2 Engage in international consortia, collaborations and policies relevant to the RWD space

□ 5.3 Actively engage in the roll-out of the EHDS to shape data collection infrastructures for the benefit of patients' access to their data

□ 5.4 Encourage alignment on RWD identification, collection and evaluation for HTA/Payer decision-making

□ 5.5 Enhance patient participation in secondary health data uses by ensuring efficient consent-based processes

□ 5.6 Educate patient communities on the importance of RWE/RWD for secondary uses □ 5.7 Engage in multistakeholder discussions on novel collection methods for patient-relevant data

□ 5.8 Explore synergies between patient group-owned disease registries and other data repositories for highly innovative medicines

**Disease Registry Holders**

□ 6.1 Explore the potential of disease registries to support regulatory and HTA/Payer decision-making

□ 6.2 Form multistakeholder partnerships to support use of data for HTA/Payer purposes □ 6.3 Support multistakeholder alignment on the role of disease registries and RWE studies in HTA in light of existing tools

□ 6.4 Profile examples of disease registries RWD supporting HTA/Payer decision-making □ 6.5 Ensure appropriate data governance and interoperability of registry-based health data for HTA/Payer purposes

□ 6.6 Align RWD standards to ensure data meets HTA needs for quality standards

**RWD Analytics Groups**

□ 7.1 Contribute to exchanges of knowledge and best practices on fit for HTA purposes RWE

□ 7.2 Promote and disseminate methodologies fit for HTA/Payer concerns in RWE uptake □ 7.3 Build RWE analytics knowledge base and support RWE assessment under EU HTA □ 7.4 Collaborate with HTA bodies on demonstration projects to help build a mutual understanding and trust in RWE

□ 7.5 Contribute to a mapping of HTA/Payer needs across jurisdictions and promote the harmonisation of fit-for-purpose methods

□ 7.6 Support HTA bodies in developing clear guidance articulating broad multistakeholder agreement

□ 7.7 Consolidate validated definitions of key aspects covering diagnoses, outcomes, covariates into a world-wide library

□ 7.8 Support industry in following published standards for RWE generation

□ 7.9 Support data custodians in standardising documentation for RWE studies

***Question 2: Tell us about your implementation story**

**When sharing your story, please include:**

- If you're sharing multiple stories, please indicate which Actions each of them refers to
- Project or initiative name (if applicable)
- Timeframe
- Brief summary of what was done (e.g. How did your project implement these Actions? What were the key activities?)
- Stakeholders involved - please describe your collaboration with other stakeholders:
- What roles did different stakeholders play? How did you engage and work together? What did you learn from this collaboration? What challenges (if any) did you face in collaborating, and how did you

  address them? Are there any publications, reports, or outputs that resulted from this collaborative work? If any, please provide links or upload them below.

- How did this advance the Stakeholder Actions you selected above? (Please be as specific as possible)
- Key outcomes, insights, or impact (What was achieved? What was learned?)
- Other challenges faced and how they were addressed (General challenges beyond collaboration, e.g. data access, resources, methods; if applicable)

***Upload any supporting materials***

*Upload file(s)*