IDERHA
integrating health data

IDERHA RWE Landscape Review: Current status of harmonisation

Disclaimer and acknowledgement

Views are my own and not that of my employer, the National Institute for Health and Care Excellence, nor any of the funding partners of the Innovative Health Initiative, or any of its affiliated entities.

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IDERHA Vision

IDERHA integrating health data

Funded by innovative health initiative

***I**ntegration of heterogenous **D**ata and **E**vidence towards **R**egulatory & **H**TA **A**cceptance*

'In IDERHA we will be an open, disease agnostic, federated data space which enables connectivity, access, use and reuse of digital health data, and develop consensus policy recommendations on health data access and heterogeneous health research (e.g. RWE) for regulatory and HTA decision-making.'

Timeline: 1 April 2023 – 31 March 2028
Partners: 32 public and private, from 10 countries in Europe

RWE Landscape Review

Policy Goal

Provide researched and consensus-driven recommendations for the acceleration of policy around use of RWD and RWE in regulatory and HTA decision-making

Landscape of Current RWD/RWE Policies

Define Policy Priorities

Engage with Key Stakeholders

Develop Recommendations

Included:

- 50 documents from 29 organizations
- Policies for:
  - Regulatory and HTA organizations
  - Medicines and Medical Devices
  - Global perspective
- 2017 to January 2024
- English text only or translations

Organizations reviewed

Regulatory
EMA (EU)
MHRA (UK)
Swissmedic (CH)

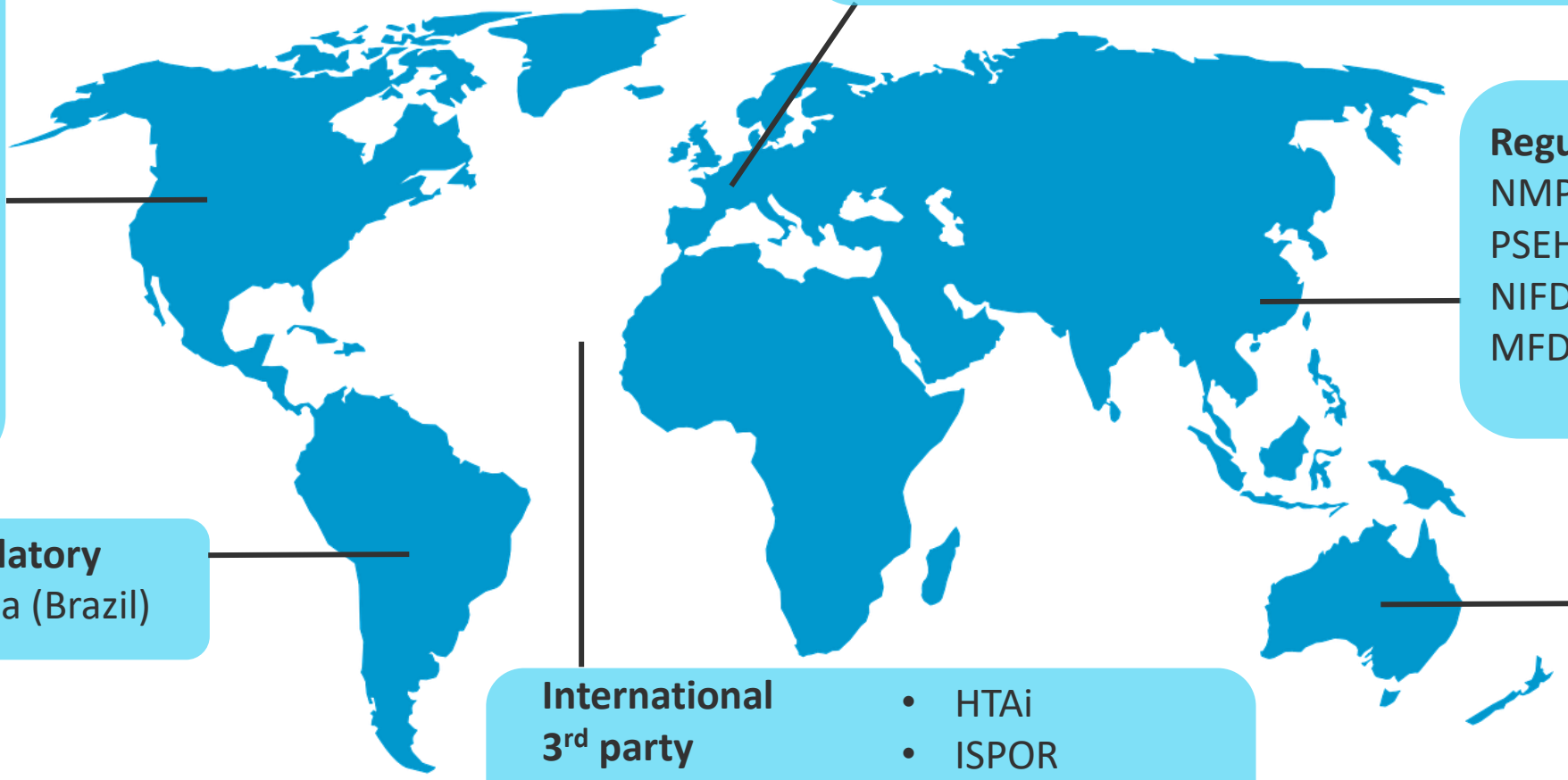
HTA
HAS (FR)
IQWiG (DE)
EUNetHTA (EU)
NICE (UK)
ZIN(NL)

3rd party
IMI (EU)

Regulatory
US FDA
Health Canada

HTA
CADTH (CAN)
ICER (US)

3rd party
Nestcc (US)



Regulatory
NMPA (CN)
PSEHB (JP)
NIFDSE (KR)
MFDS (KR)

HTA
REALISE working group (mixed)

Regulatory
Anvisa (Brazil)

Regulatory
TGA (AUS)

International
3rd party
- ICH
- IMDRF
- HTAi
- ISPOR
- ISPE
- OHE

Key Findings

- Breadth and depth of policies vary considerably across geographic regions
- More regulatory policies than HTA at this stage
- Regulatory policies tend to be more detailed (not always!)
- More policies related to medicines than devices

50 documents in review:
- 32 Regulatory
- 14 HTA
- 4 Both

Key Findings – emerging areas of convergence

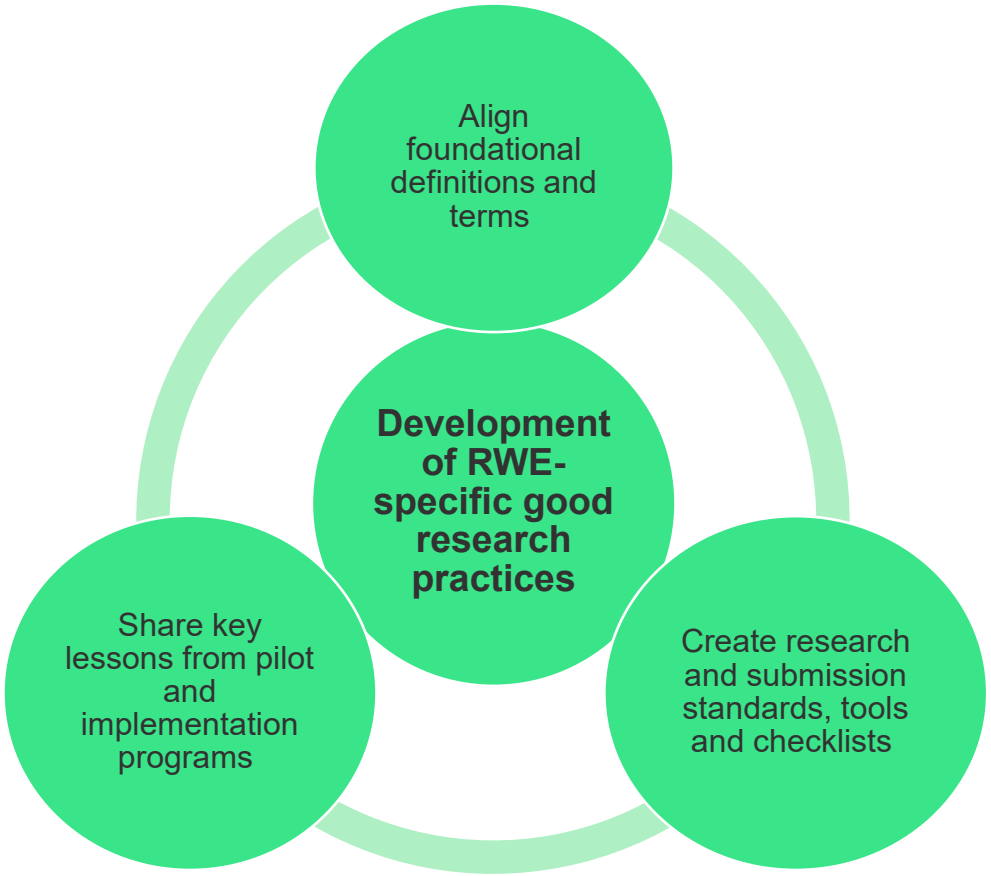
- Agreement on benefits of RWE and persisting concerns
- General consistency in how and when RWE should be used
  - Use to provide information on ‘real-life’ results, contextualization, post-market surveillance
  - RWE positioned as complimentary to clinical trials – however examples of both regulators (US FDA) and HTA bodies (NICE) accepting RWE as primary evidence for medical devices/medtech
- Development of ‘good research practices’ for RWE
  - Core principals behind use of RWE are aligned
    - High quality data
    - Transparent processes

Where is there a lack of convergence?

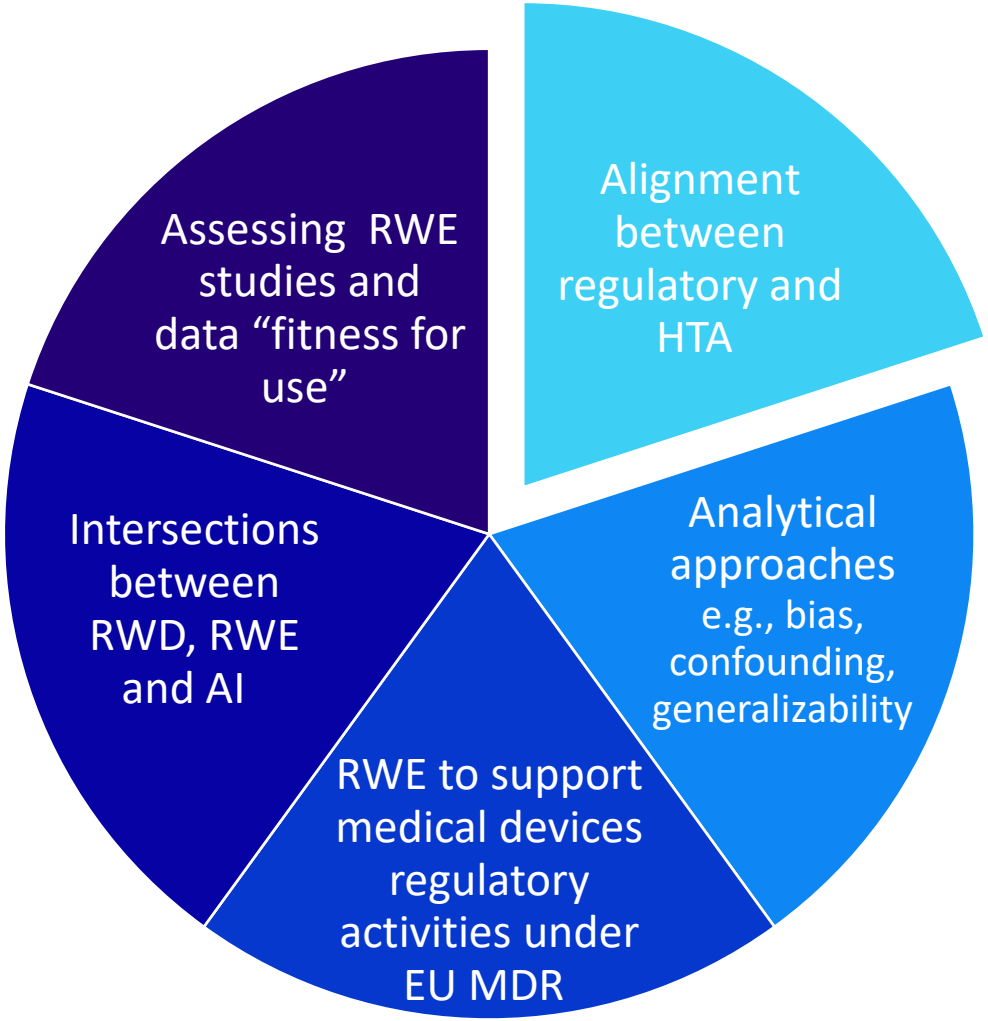
- Regulatory guidance tend to be more prescriptive
- Assessment of data quality/fitness-for purpose
  - Lack of consistent criteria
  - Different evidentiary bars
- Analytical methods
  - Not unexpected
  - Differing remits

- Lack of convergence – or lack of explicit guidance?
- General differences across policies not specific to HTA vs. Regulatory

Emerging Best Practices

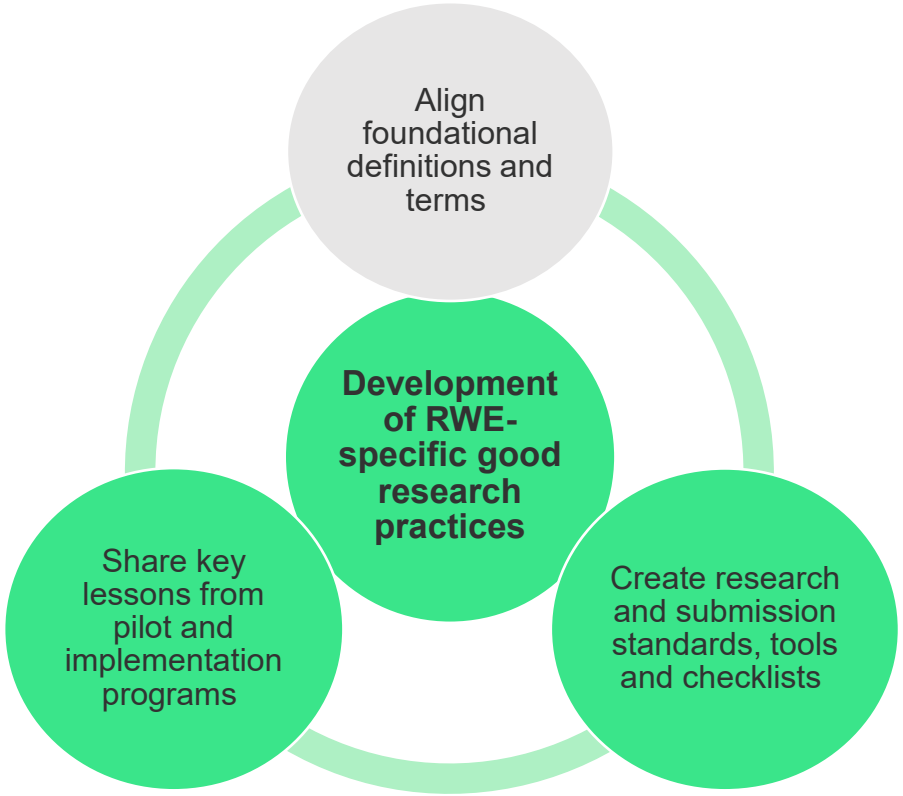


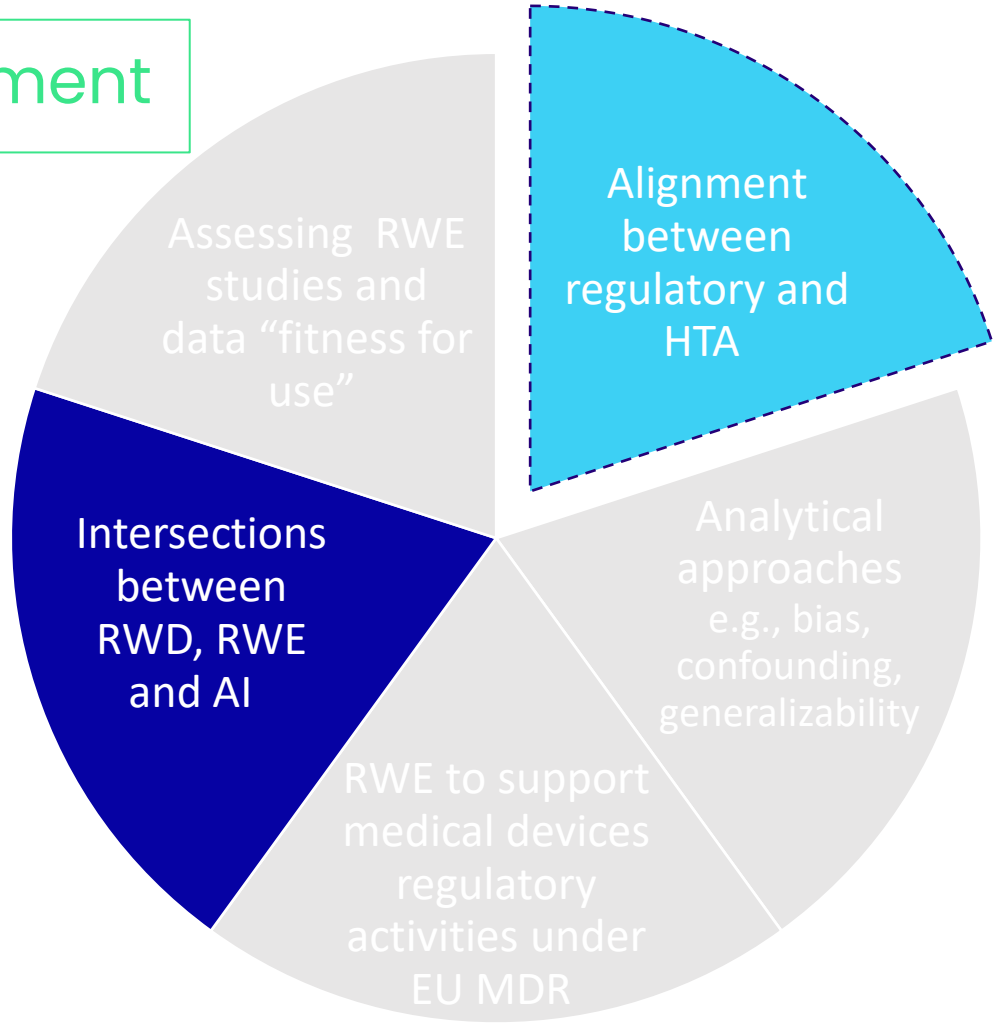
Key Policy Gaps



What is IDERHA doing to address this?

First phase recommendation development





Read our full report

- Landscape Analysis | IDERHA
- IDERHA website > Policy Development > Landscape Analysis
- Thank you for listening!

Contact: Katharine.Cresswell@nice.org.uk