

# From In-House Coding to Global IMDRF Convergence

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# IMDRF coding



Data fragmented across countries

Based on non-comparable national terminology

Difficult to aggregate and trend globally

Narrative based reporting.  
Limited signal detection

Harmonized AE Terminology

- Medical Device and IVDs

Consistent interpretation

- Device Problem, cause, impact on Patient, etc)

Strengthen health protection

- Better post-Market Surveillance

# From Internal to Global Language



## Importance

Harmonized complaint coding enables effective post-market surveillance and supports patient safety globally

1



## Challenges

Fragmented or proprietary terminology limits the ability to detect safety signals and delays regulatory actions.

2



## Role

The IMDRF framework provides a structured vocabulary that ensures data comparability across regions and regulators.

3

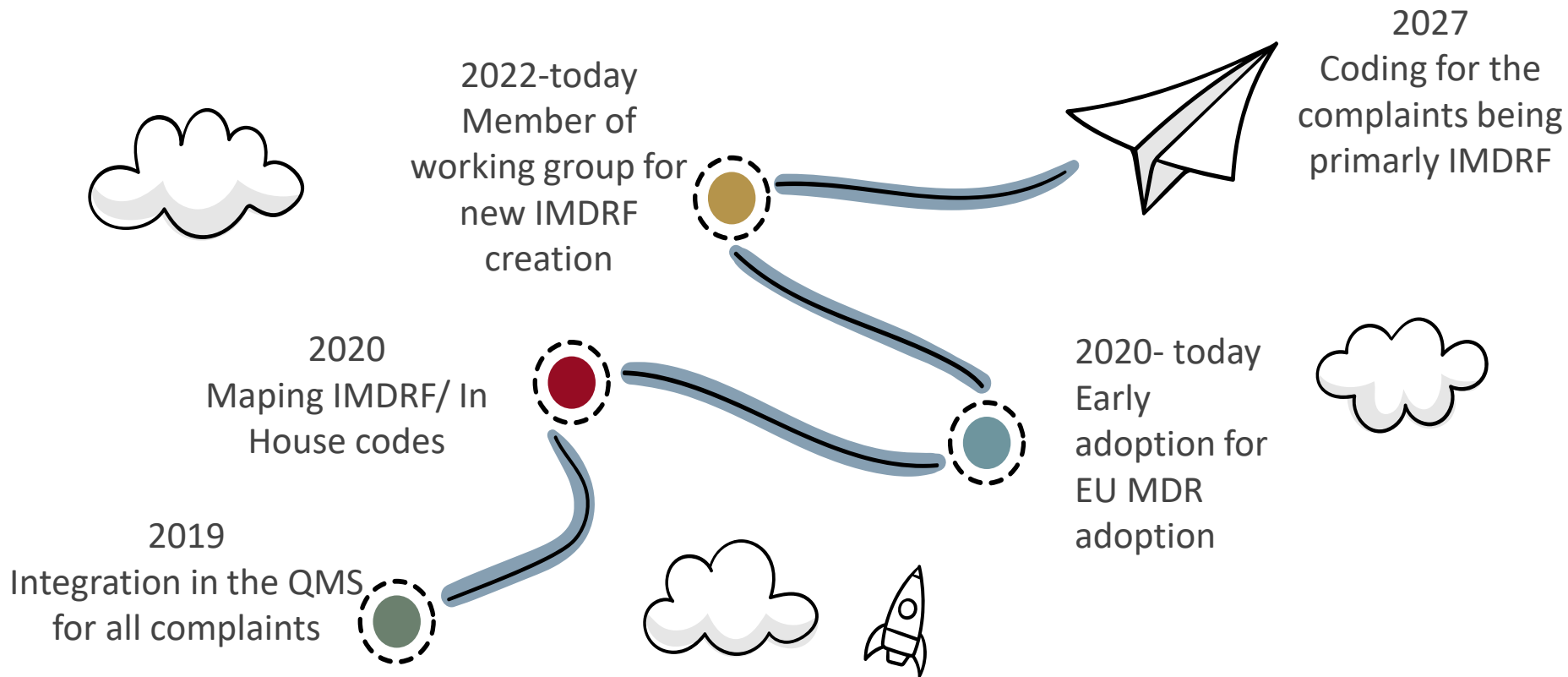


## Focus

Early adoption of harmonized coding reflects commitment to regulatory trust and mature quality systems.

4

# Edwards Strategy for adoption



# Lesson learned

## Systematic mapping

- One-to-one mapping was not always possible due to: Different levels of granularity
- Mapping rules had to be **clinically and technically validated**, not automated only

## Trend Integrity protection

- A key risk identified early: **artificial trend changes due to coding migration**
  - Mitigation actions: Parallel trending during transition period
  - Retrospective alignment for key signals
  - Clear traceability when trend shifts were coding-driven, not risk-driven

## Continuous maintenance is required

- Annual IMDRF updates introduce new codes and refinements
  - Version control
  - Mapping updates

# From adopters to Contributors



**IMDRF  
2023-2025  
CODES**



**IMDRF ASK FOR  
MANUFACTURERS  
FEEDBACK NEW CODES**



**EDWARDS PROPOSED  
25 NEW CODES**



**IMDRF ACCEPTED 14 PROPOSAL: NEW  
CODES AND MODIFICATIONS OF  
PREEXISTING CODES**



**Edwards**