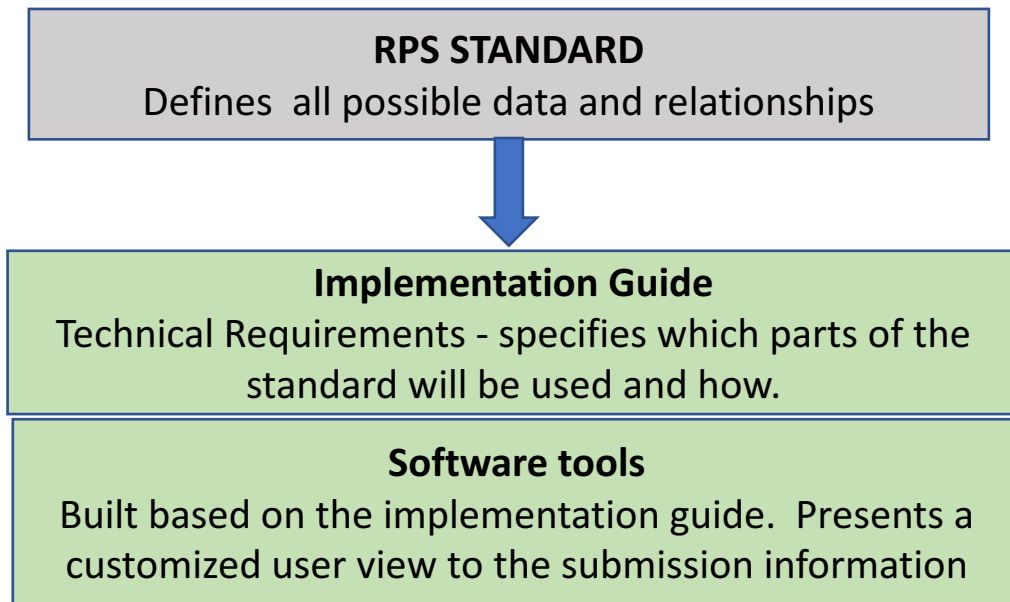


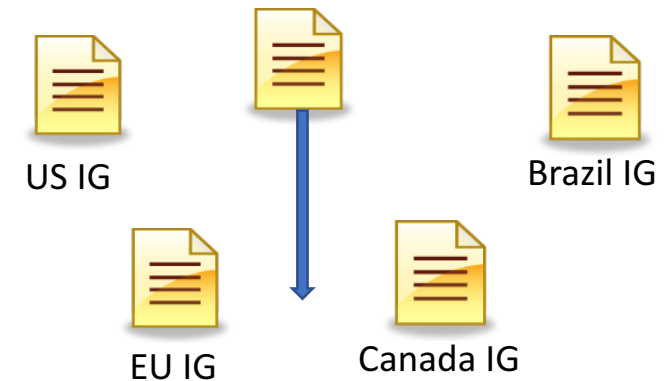
# RPS Next Steps

# RPS Implementation Work

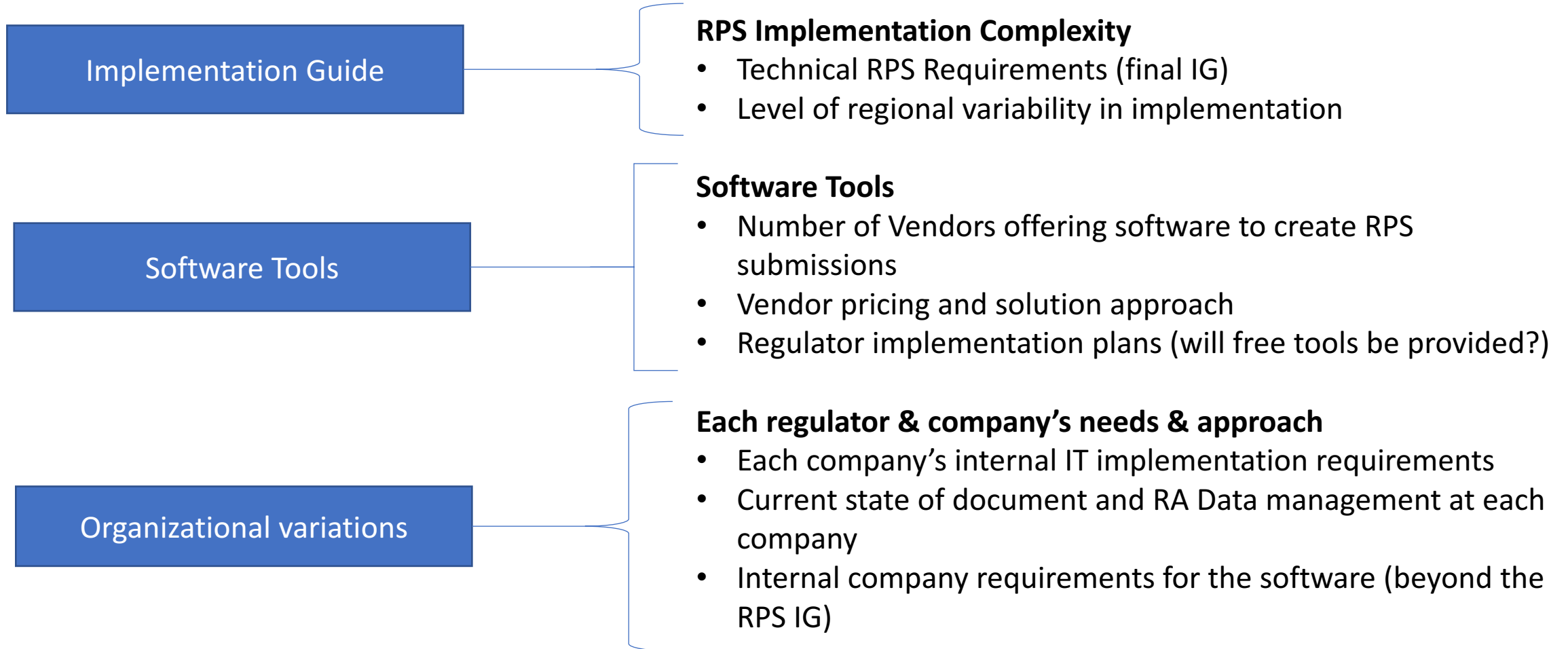


## IMDRF Harmonized Implementation Guide (IG)

The harmonized IG is the basis for the regional IGs.



# Challenges in Quantifying Cost - Benefit



# Implementation Phases

| Work Phase & Outcome                                    | Timing     | Information Available / Stakeholder Engagement   |
|---|------------|--|
| <b>Scope &amp; Process Definition:</b>                  | Ongoing    | <ul style="list-style-type: none"><li>• Types of submissions in scope by region</li><li>• High level understanding of structured information required in an RPS submission</li></ul>   |
| <b>Draft IG Preparation</b>                             | March 2018 | <ul style="list-style-type: none"><li>• Harmonized IG available for open consultation</li><li>• Harmonized controlled vocabulary available for open consultation</li><li>• Vendor discussions / engagement</li></ul>   |
| <b>Testing</b>  | Sept 2018  | <ul style="list-style-type: none"><li>• Ongoing vendor discussion / engagement</li><li>• Visibility to test scenarios &amp; results</li></ul>  |
| <b>Implementation Approach &amp; Governance Process</b> | TBD        | <ul style="list-style-type: none"><li>• Final IG</li><li>• Regional IGs available for review &amp; comment</li><li>• Regulator implementation plans available for open consultation</li><li>• Draft IMDRF Governance process for discussion / review</li></ul> |

# Points for Industry Engagement

- Preliminary discussion of scope & impact of scope to industry
- Open discussion and active review of the draft harmonized IG and draft controlled vocabulary.
  - Provide feedback to the WG.
  - Each company begin to assess impact based on information required in an RPS message and the information they currently track & store
- During testing:
  - industry may begin to have discussions with vendors to assess plans and potential tools that will be available for purchase
  - Review test results for insights into how RPS will be used and potential challenges
- Open dialog and comment on regulator implementation plans & the governance process
- Individual companies do their own cost analysis as part of the implementation plan review