IMDRF International Medical Device Regulators Forum

Guidance Structure and Key Proposal - overview -

Optimizing Standards for Regulatory Use

IMDRF/Standards WG/N51 FINAL: 2018

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IMDRF Standard WG

PMDA, JApan

IMDRF International Medical Device Regulators Forum

GHTF/SG1/N44: 2008 "Role of Standards in Assessment of Medical Devices"

IMDRF/Standards/N51: 2014 "Final Report: List of International Standards Recognized by IMDRF Members as of March 2014"

Report: Improving the Quality of International Medical Device Standards for Regulatory Use

IMDRF/Standards/N51: 2018 "Optimizing Standards for Regulatory Use"

Implementation

NWIP

SOP for liaison structure with ISO/IEC

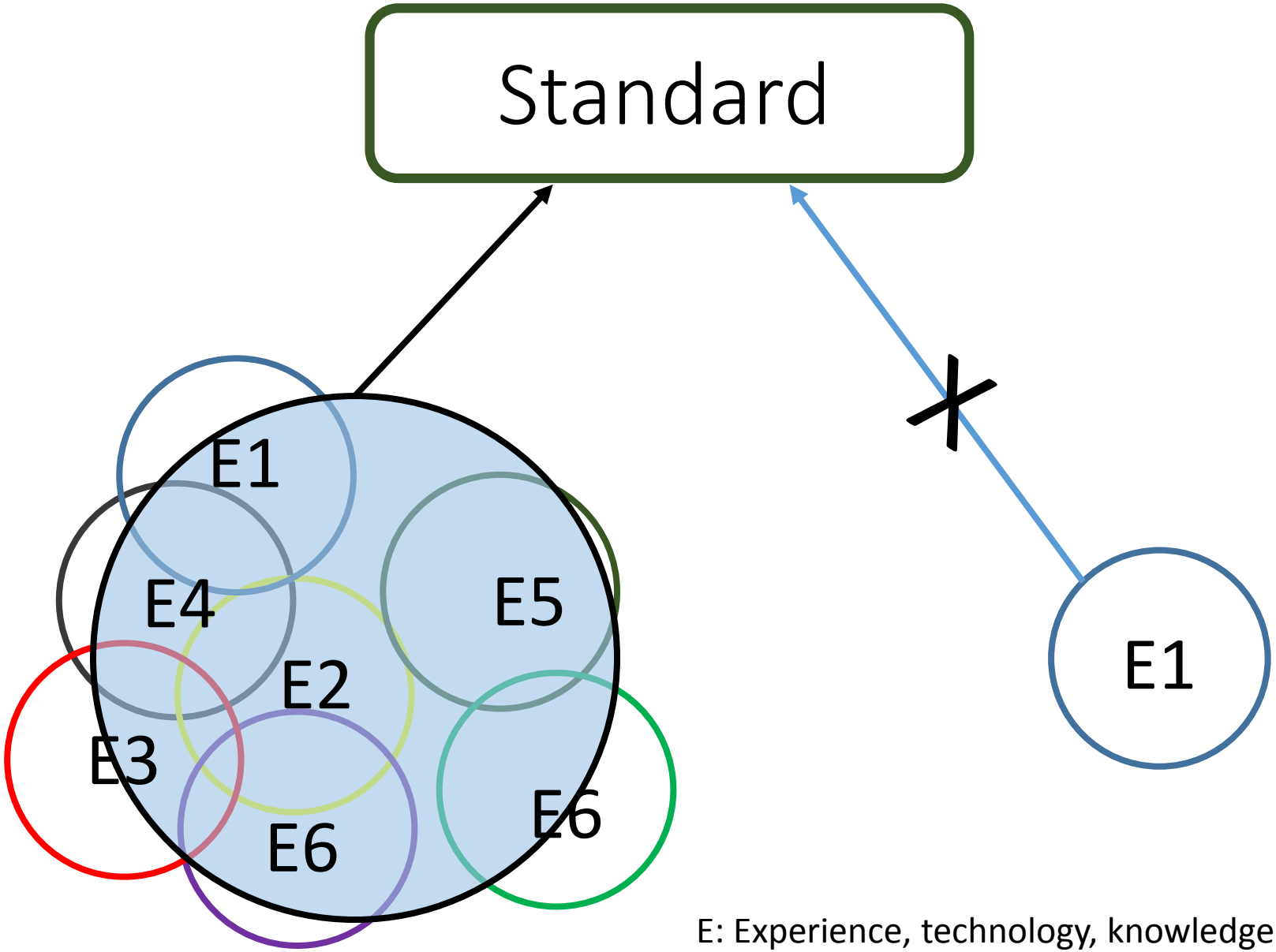
List of International Standards Recognized by IMDRF Members as of 2018/2019

Survey on standard recognition policy

Future

Best practices and policies for the use and recognition of standards

Empowers IMDRF goal of harmonized regulatory approaches



E: Experience, technology, knowledge

IMDRF Essential Principles

- The IMDRF EPs provide **broad, high-level criteria for design, production, and postproduction (including post-market surveillance) throughout the life-cycle of all medical devices.** They provide **a framework for regulatory expectations and represent a consensus on fundamental design and manufacturing requirements** that, when met, indicate that a medical device is safe and performs as intended and offers significant benefit.

"IMDRF Essential Principles"

Chapter 4: General Principles

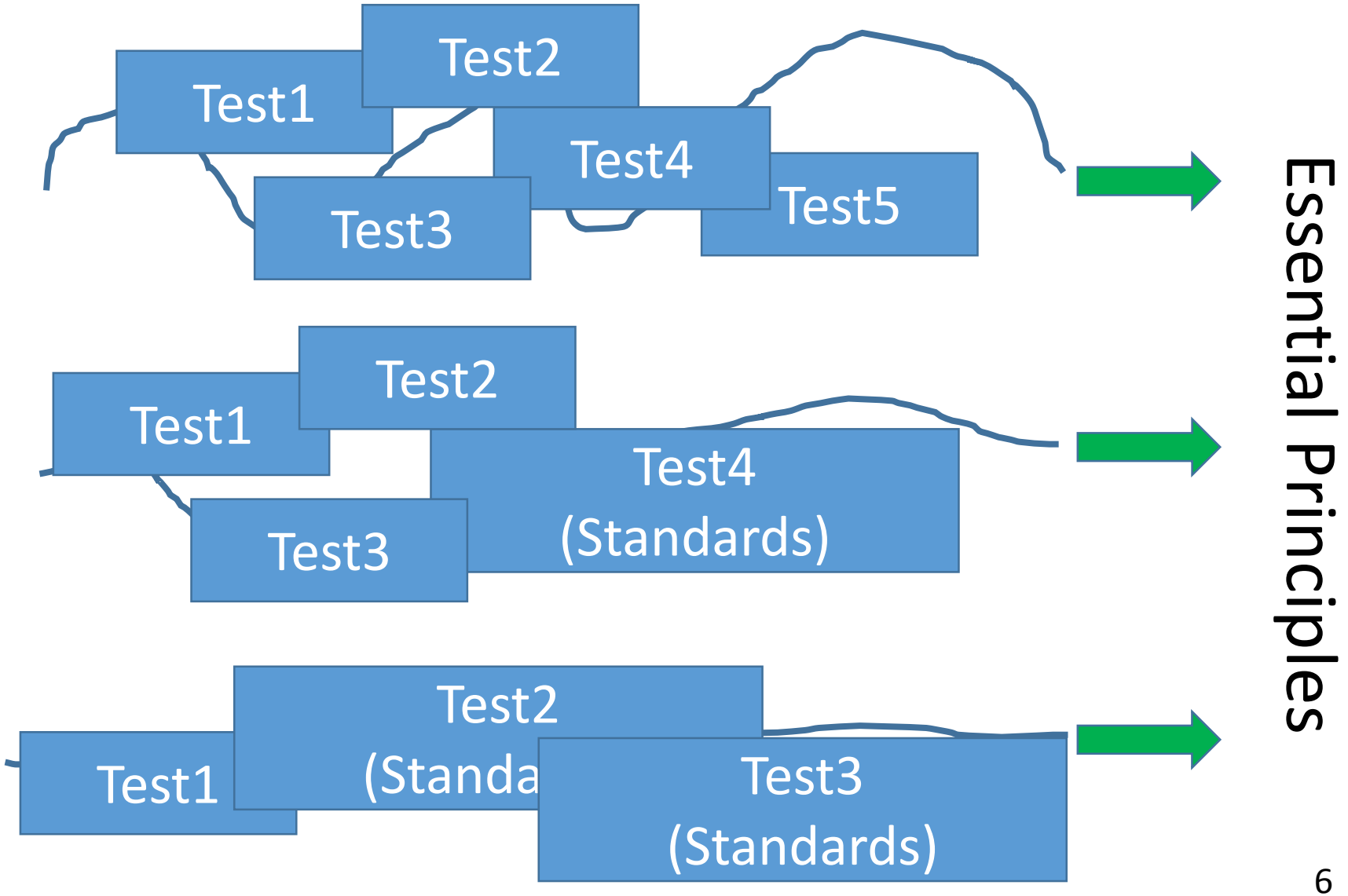
Chapter 5: Essential Principles Applicable to all Medical Devices and IVD Medical Devices

Chapter 6: Essential Principles Applicable to Medical Devices other than IVD Medical Devices

Chapter 7:Essential Principles Applicable to IVD Medical Devices

Appendix A: Use of Standards in Meeting Essential Principles

Appendix B: Guidance on Essential Principles


Test1
Test2
Test3
Test4
Test5
Test1
Test2
Test3
Test4
(Standards)
Test1
Test2
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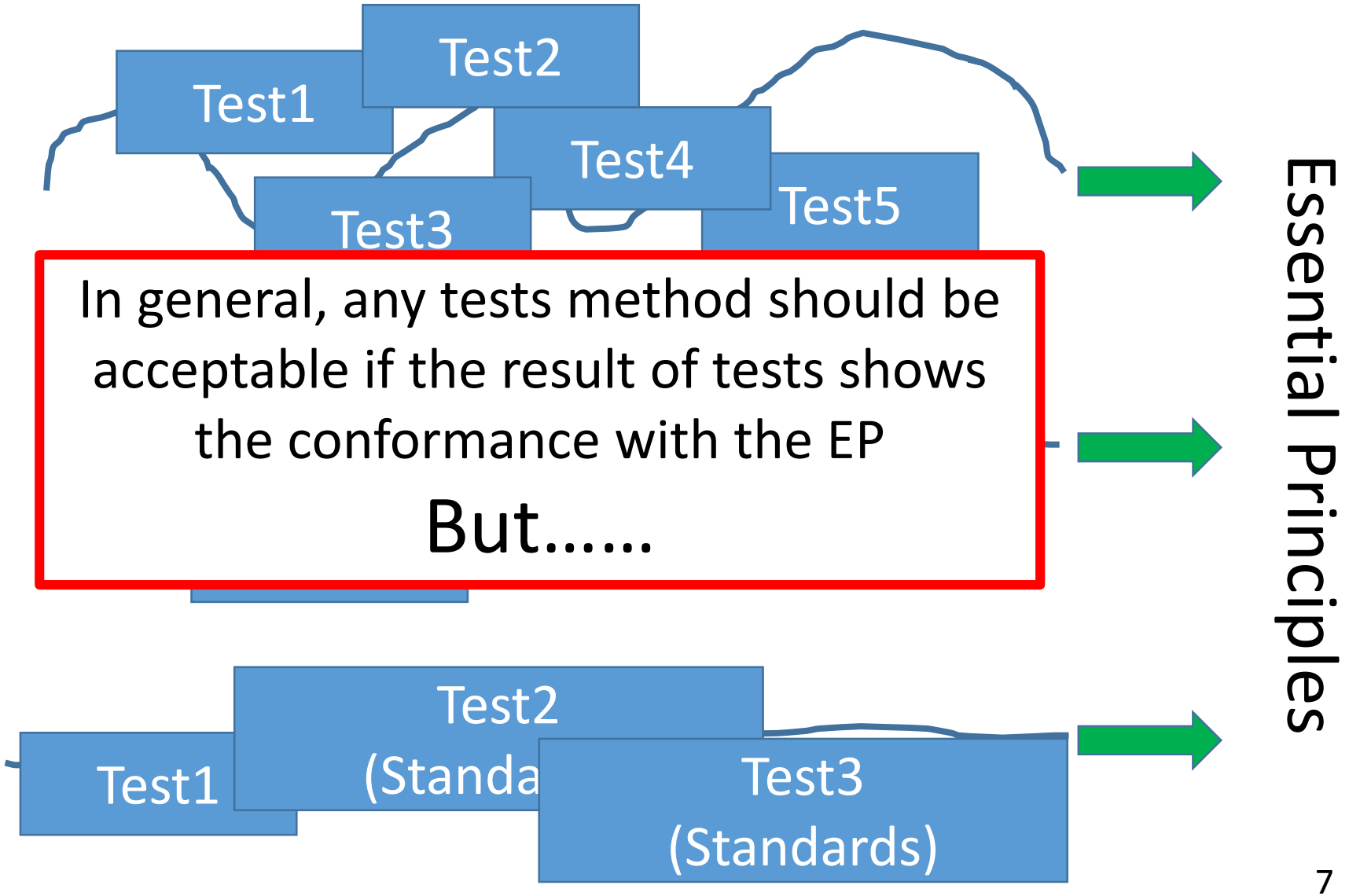
Test3
(Standards)
Essential Principles

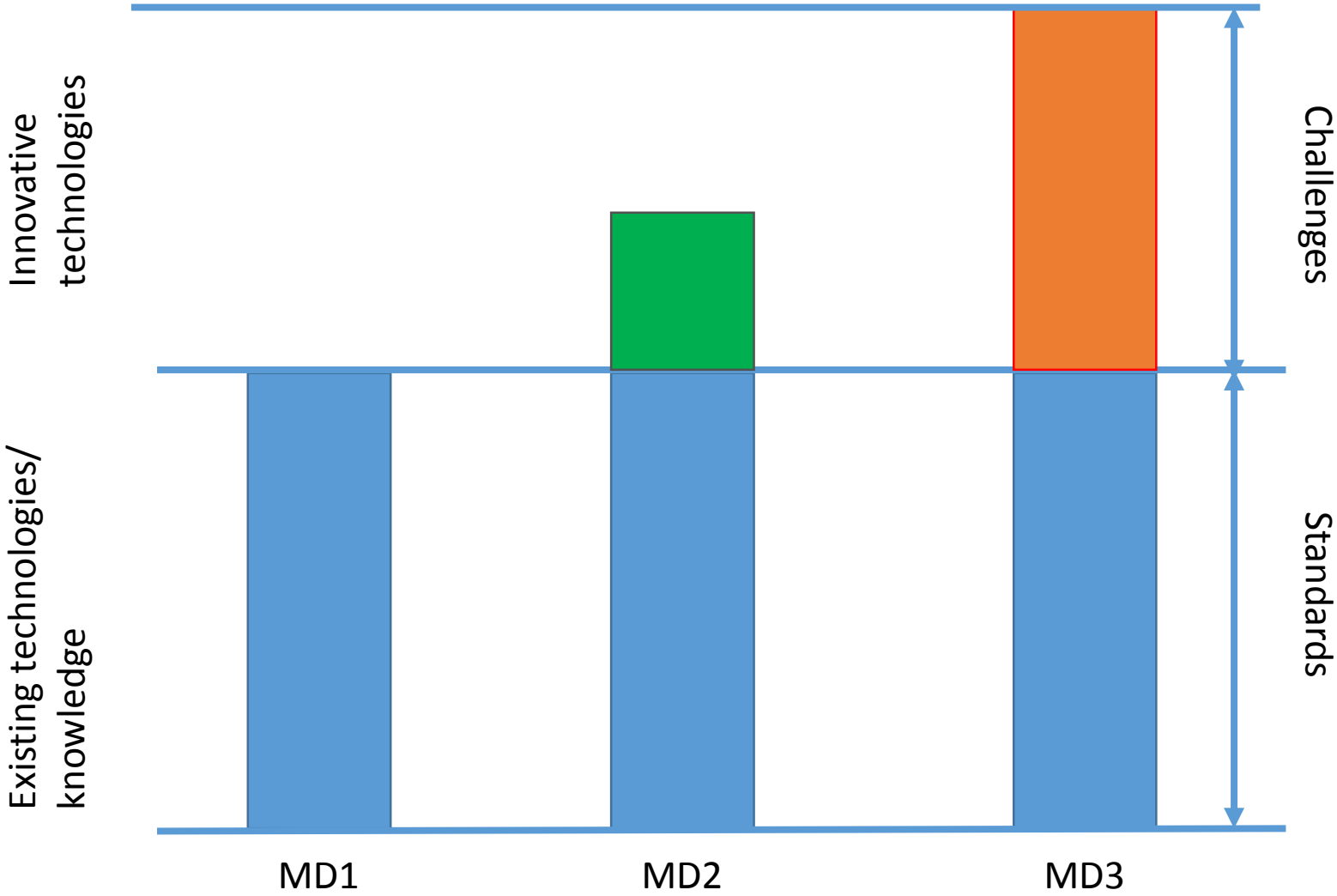

Test1
Test2
Test3
Test4
Test5
In general, any tests method should be acceptable if the result of tests shows the conformance with the EP
But……
Test1
Test2
(Standa
Test3
(Standards)
Essential Principles

The use of consensus standards

- Enhance transparency
- Reduce duplication
- Reduce oversight

Enhancing quality of application/review
Time saving
Cost saving

Technologies and Standards



IMDRF International Medical Device Regulators Forum

Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 25 September 2018

Yuan Lin, IMDRF Chair

How to improve standards and standards developing processes for use in device review

- Two elements
  - Improving standards' content to enhance utility for regulatory purposes
  - Encouraging regulatory authority participation in standards development
- Public consultation
- Publication October 2018

- Audience
  - Regulators
  - SDOs
  - Medical device community
- Scope
  - Resource for standards writers and regulators
  - All medical devices, including IVD

Main Chapters

- ✓ General
- ✓ Recommendation for Standards Development
- ✓ Enhancing Stakeholder Participation in Standards Development
- ✓ IMDRF and Standards Developing

General

1. Standards should map to *IMDRF Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (2018)*
2. Performance versus design stipulations
3. Characteristics for optimized international standards

General

1. Map to IMDRF *Essential Principles*

- Standards should reflect:
  - A close relationship between the standard's scope and one or more of the IMDRF EPs
  - The clarity and completeness of the requirements contained in the standard as it relates to a specific EP
  - Test methods for determining compliance with each of the requirements in the standard, and clear acceptance criteria for determining that each technical requirement is met

General

2. Performance versus Design Stipulations

- Express a standard's requirements with references to performance, rather than to specific device features
- Fosters innovation and healthy marketplace dynamics
- An example from the *ISO/IEC Directives Part 2* illustrates this principle:

> *Different approaches are possible in the specification of requirements concerning a table:*
>
> *Design requirements: The table shall have four wooden legs.*
>
> *Performance requirements: The table shall be constructed such that [the table top remains level and at its original height] when subjected to … [stability and strength criteria].*

General

3. Characteristics

- **Consensus:** standards should be written under conditions that promote accessibility, transparency, broad representation and consideration of interests through consultations.
- **Fairness:** the needs of all stakeholders, including regulators, are considered in standards development.
- **Compatibility:** standards are compatible with the internationally accepted principles of safety and performance of medical devices.
- **State of the art:** standards represent the state of art in a technological field.

General

3. Characteristics (cont'd)

- **Efficiency:** they should also promote economic benefits, e.g., reducing redundant reporting requirements, streamlining regulatory activities and harmonizing expectations across different countries and regions.
- **Completeness**: within its scope, a standard address all predictable elements related to Essential Principles of device safety and/or performance.
- **Verifiability**: requirements include verifiable objective measurements.
- **Repeatability**: testing methods in standards will yield consistent results across different certified test houses.
- **Consistency**: terms and symbols across standards are as consistent as possible.
- **Clarity**: standards are clear, unambiguous, and easily understood.
- **Accessibility**: standards and associated documents should be reasonably available to relevant stakeholders.

Recommendation for Standards Development

1. Optimizing standards content
2. Best practices for standard development procedures
3. Use of standards in meeting IMDRF Essential Principles

Recommendation for Standards Development

1. Optimizing Standards Content

- Standards should be crafted so that conformity to them can reduce regulatory burden, demonstrate conformance to IMDRF's EPs, and feature:
  - A strong rationale that:
    - Explains the general requirements and identifying test methods and/or other means of demonstrating compliance
    - Demonstrates how conformance to the standard achieves its goal of satisfying the associated EPs
  - Summary of the type of stakeholder groups involved in the drafting and editing of the standard
  - Identification of risk and direction on how to address
  - A clear scope
  - Terms and definitions established and accepted in other standards
  - Means to assess clinical performance if applicable as part of the normative requirements

Recommendation for Standards Development

1. Optimizing Standards Content

- Standards should feature (cont'd):
  - Clear and quantitative acceptance criteria that can adequately support IMDRF EPs
  - Explanation of how conformance can be met if no acceptance criteria are included
  - If acceptance criteria not mandatory, justification for why, and how to demonstrate conformance to the standard
  - Well accepted and verified test methods (including for new or unfamiliar methods)
  - Transparent and clear (e.g., 'track changes') revisions
  - An annex or table that cross references the standard's clauses to the Essential Principles

Recommendation for Standards Development

2. Best practices

- Consider regulatory requirements at every step
- Write a strong Business Plan
  - Robust needs analysis: market, safety, regulatory
  - Expectations for regulatory utility
  - Emphasize conformity assessment
- Encourage and solicit a wide variety of expertise
- Get involved – early!

Enhancing Stakeholder Participation in Standards Development

1. International, regional and national level participation: joining the conversation
2. Recommendations for participation: submitting effective comments

Enhancing Stakeholder Participation in Standards Development

1. Joining the conversation

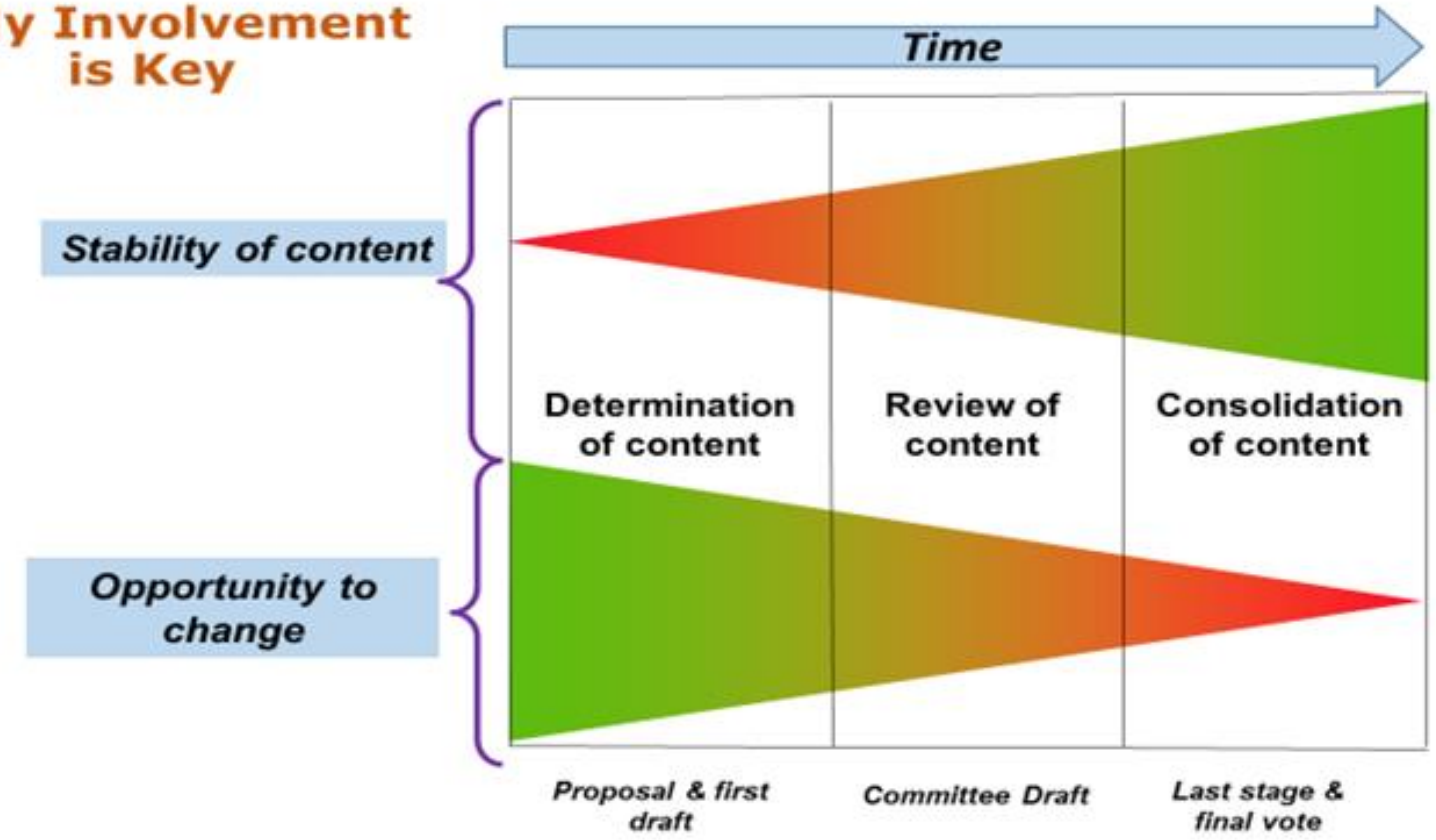
- Regulators should build a strong standards program that encourages contributions to standards development
- Engagement with SDOs is essential
  - Through National Bodies and Mirror Committees
  - On SDO Technical Committees
- Contribute regulatory perspective
- Consider leadership roles

Enhancing Stakeholder Participation in Standards Development

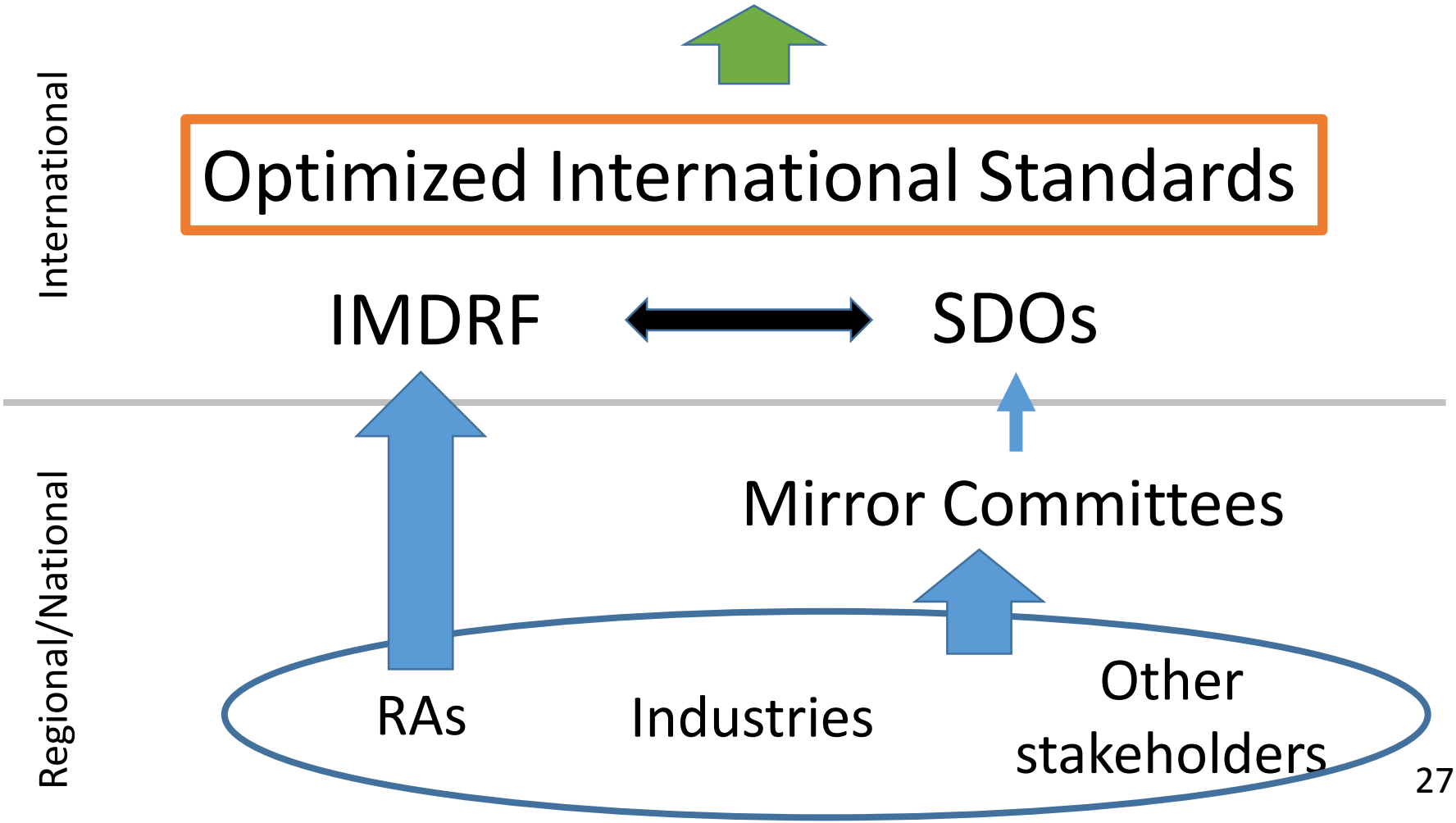
2. Submitting effective comments

- Get involved early (at NWIP stage) and remain engaged throughout the entire process
- Become familiar with the draft
- Listen to others, consult regulatory colleagues
- Consider impact on regulatory processes, especially conformity assessment, testing methods and audit requirements
- Articulate your position clearly and concisely
- Use SDO's approach and templates
- Offer alternative language

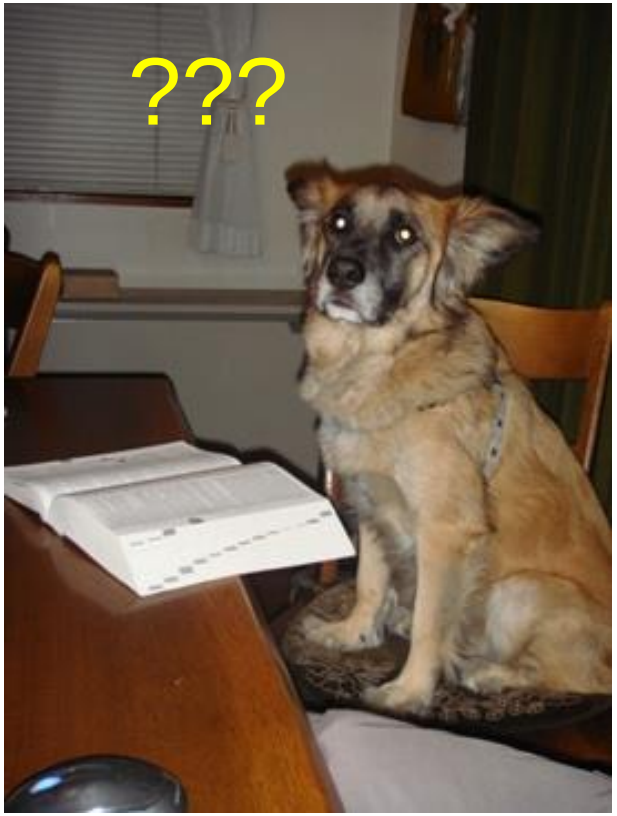
Early Involvement is Key



IMDRF *Essential Principles*



Any Questions?



Thank you!!