



FDA Perspective on Scientific Review of Novel Technologies for Detection of Resistance

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Disclaimer

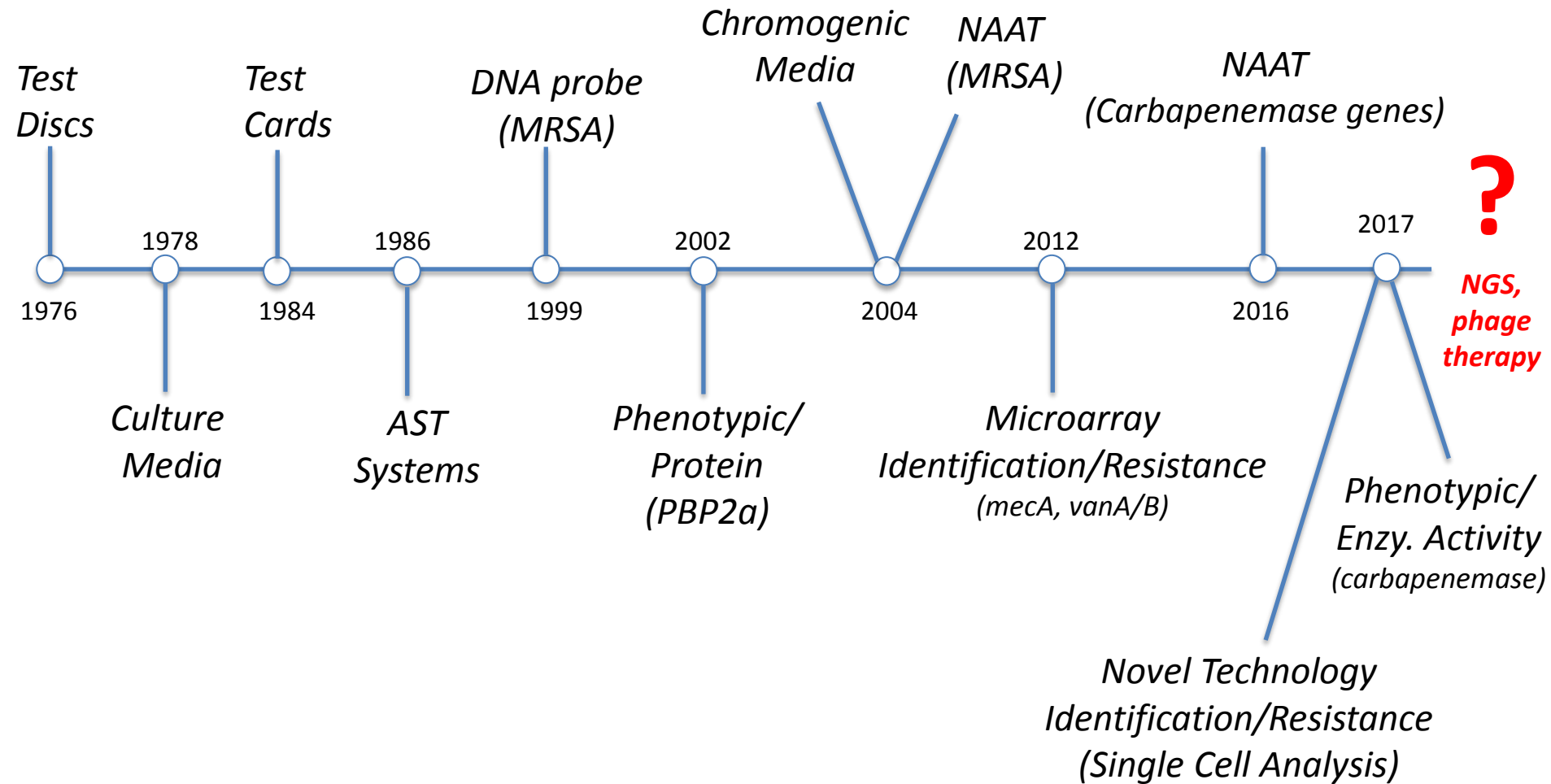


The contents of this presentation are for discussion and summary purposes only and do not describe the full extent of requirements applicable to devices under discussion in this workshop. Please see the Federal Food, Drug, and Cosmetic Act and Chapter I of Title 21 of the Code of Federal Regulations (CFR), especially Subchapter H that has requirements specific to medical devices.

Outline

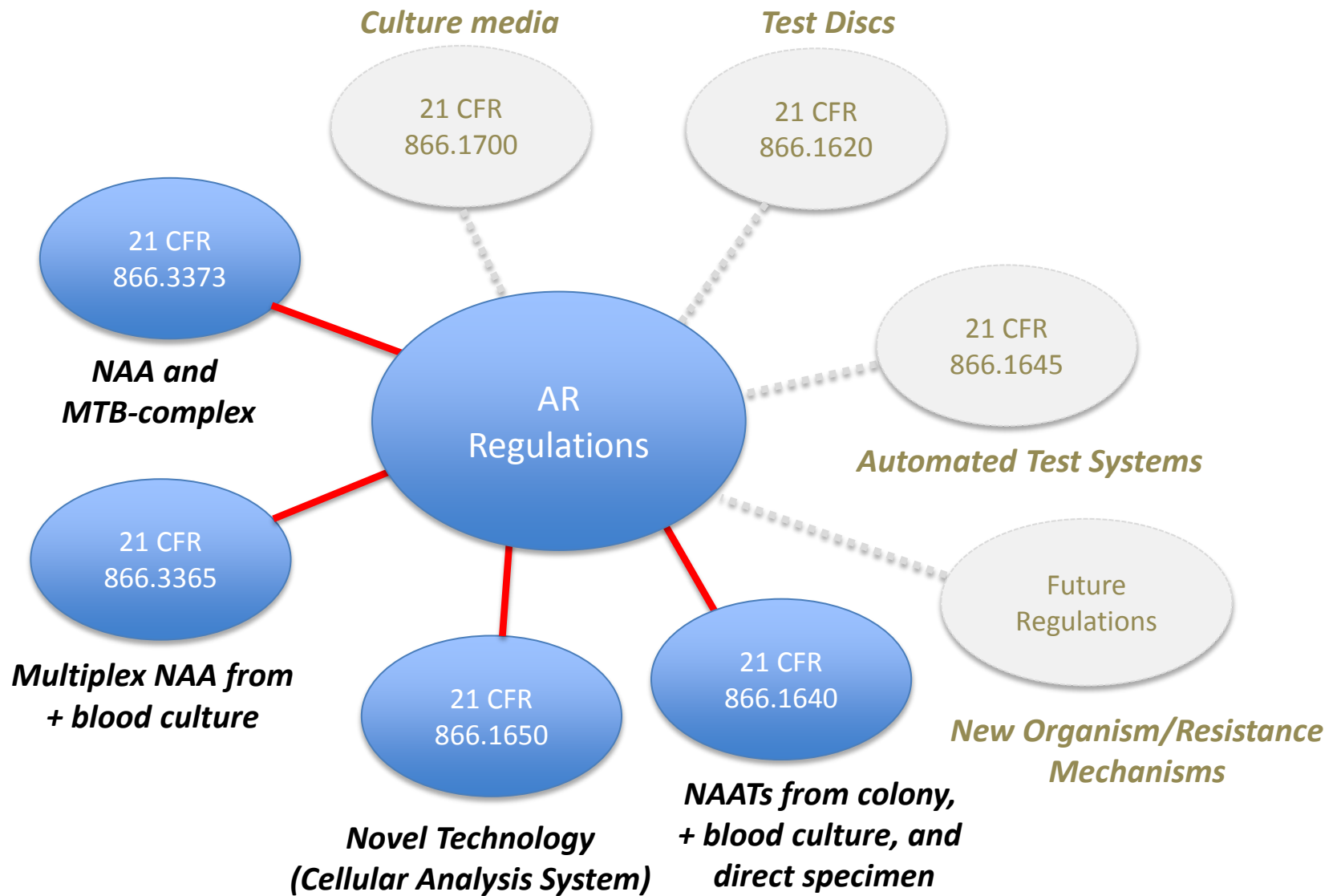
- Devices for Detection of Antimicrobial Resistance and FDA Experience with Submitted Applications
- Advances in Diagnostic Devices for Detection of Resistance Markers and Associated Challenges
- Resources Available to Aid in Evaluating New Technologies
- Summary

Timeline of AR Test Clearances



Is This a Golden Era for Developing Diagnostic Devices?

Different Regulations for ASTs



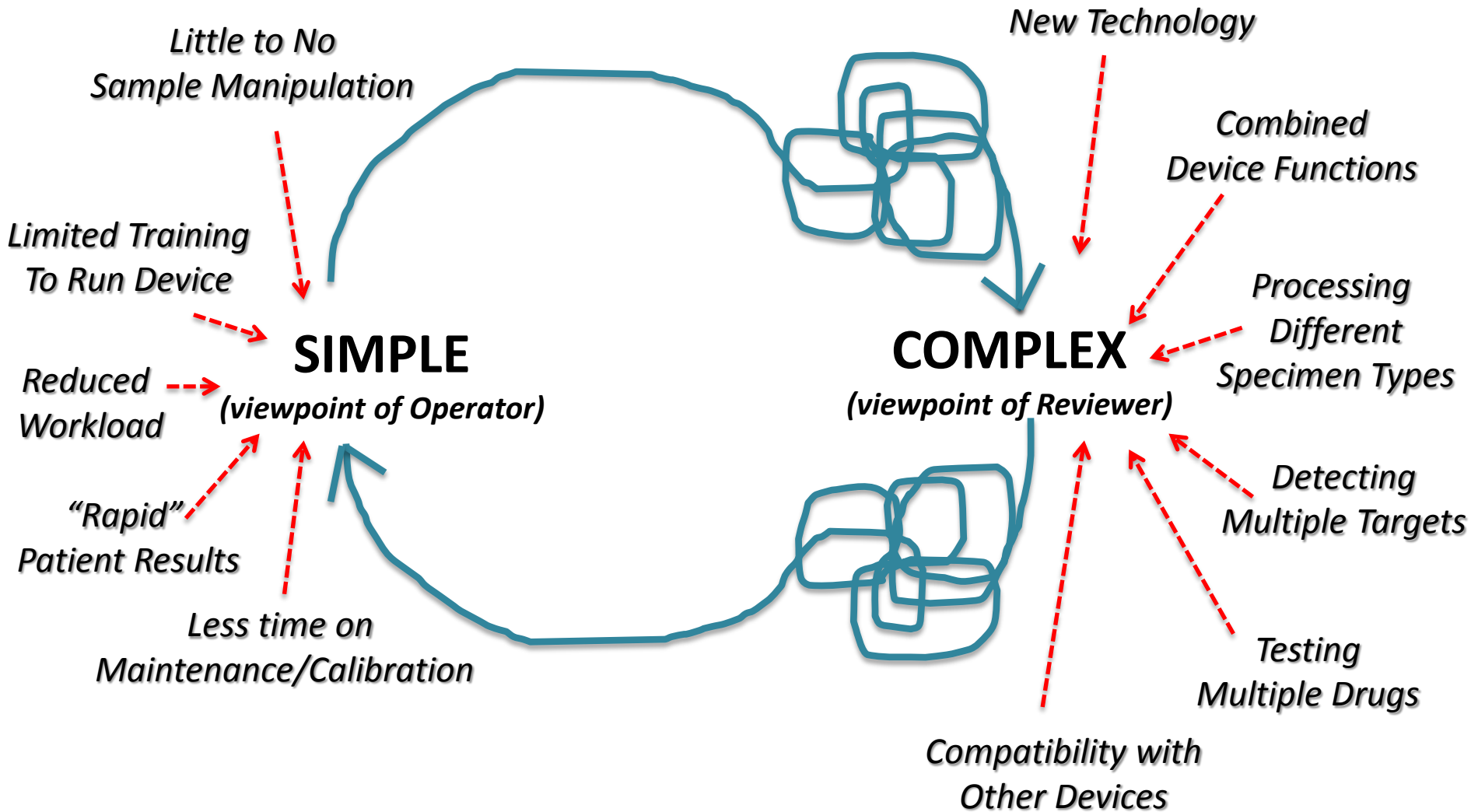


Device Clearances: AST and Detection of Resistance & Markers 2011-2016*

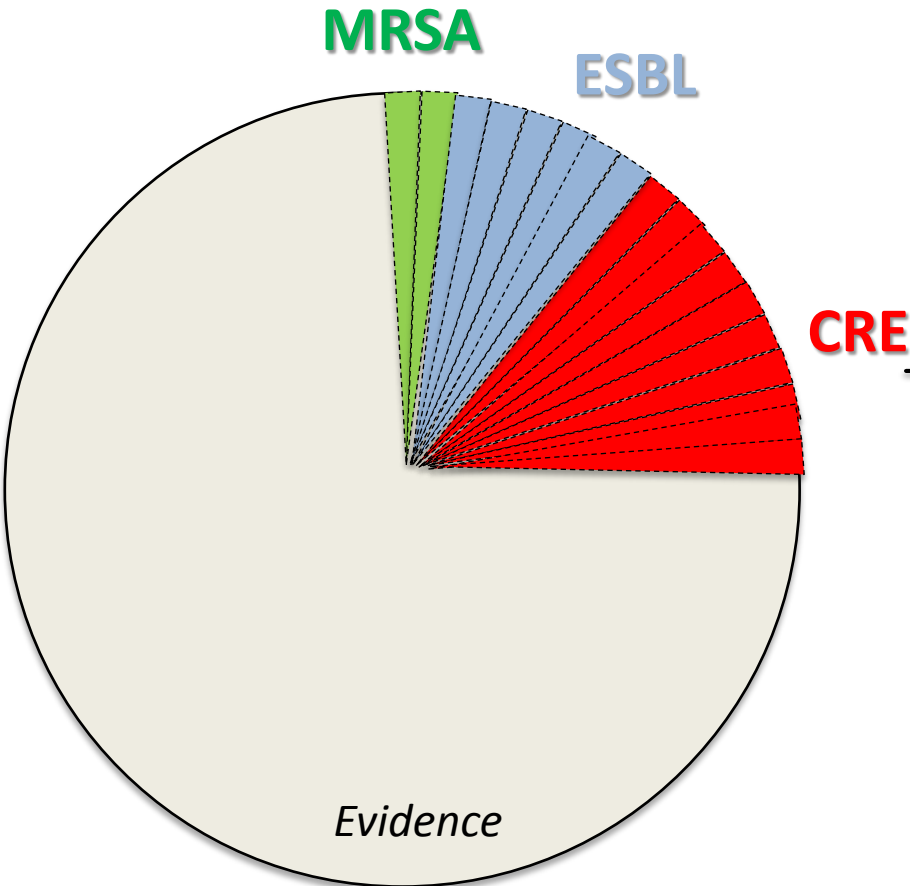
Year	Phenotypic	Molecular	Immunologic	Total
2011	23	3	0	26
2012	13	3	1	17
2013	9	6	0	15
2014	14	3	1	18
2015	13	2	0	15
2016	12	5	0	17
Total	84	22	2	108

*Does not include pre-submissions

The Shift in Technology is Having a Dual Effect



Challenge: Level of Evidence to Support Claims



What to Consider:

- Intended Use(s)
- Colonies versus direct from specimen
- Species (Types and Number)
- Multiple Genes
- Multiple Gene Variants
- Prevalence
- Different Resistance Mechanisms
- Balance—Wet-testing vs *in silico*
- Comparator Method
(*molecular, phenotypic, Composite Reference*)
- Validation of New Comparator Methods
- Presentation of Data (Amount of Data)
- Results Interpretation /Labeling

Issues Encountered During Our Review of Molecular Submissions



- Determining an appropriate Reference Method for a molecular investigational device
- Assessing organism/resistance marker identification in the context of specimen types with known bacterial flora (colonizers vs. infection)
- Reporting of resistance markers without organism identification and what to communicate to end-users
- Presenting the detection of gene variants given the dynamic nature of antimicrobial resistance, prevalence, and new variants identified

Meeting the Challenge

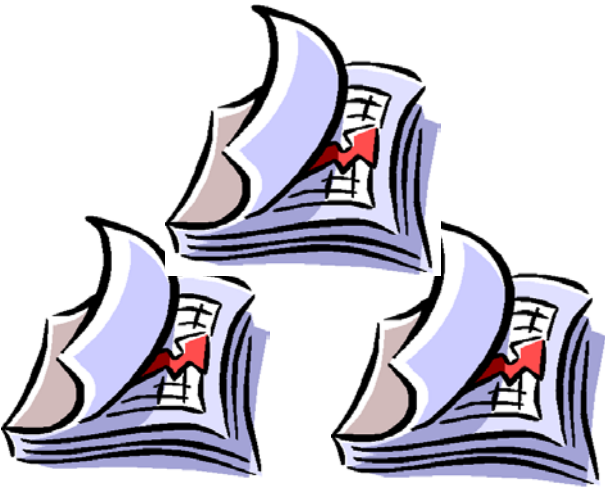
(Review Teams)



1 Submission



1 Reviewer

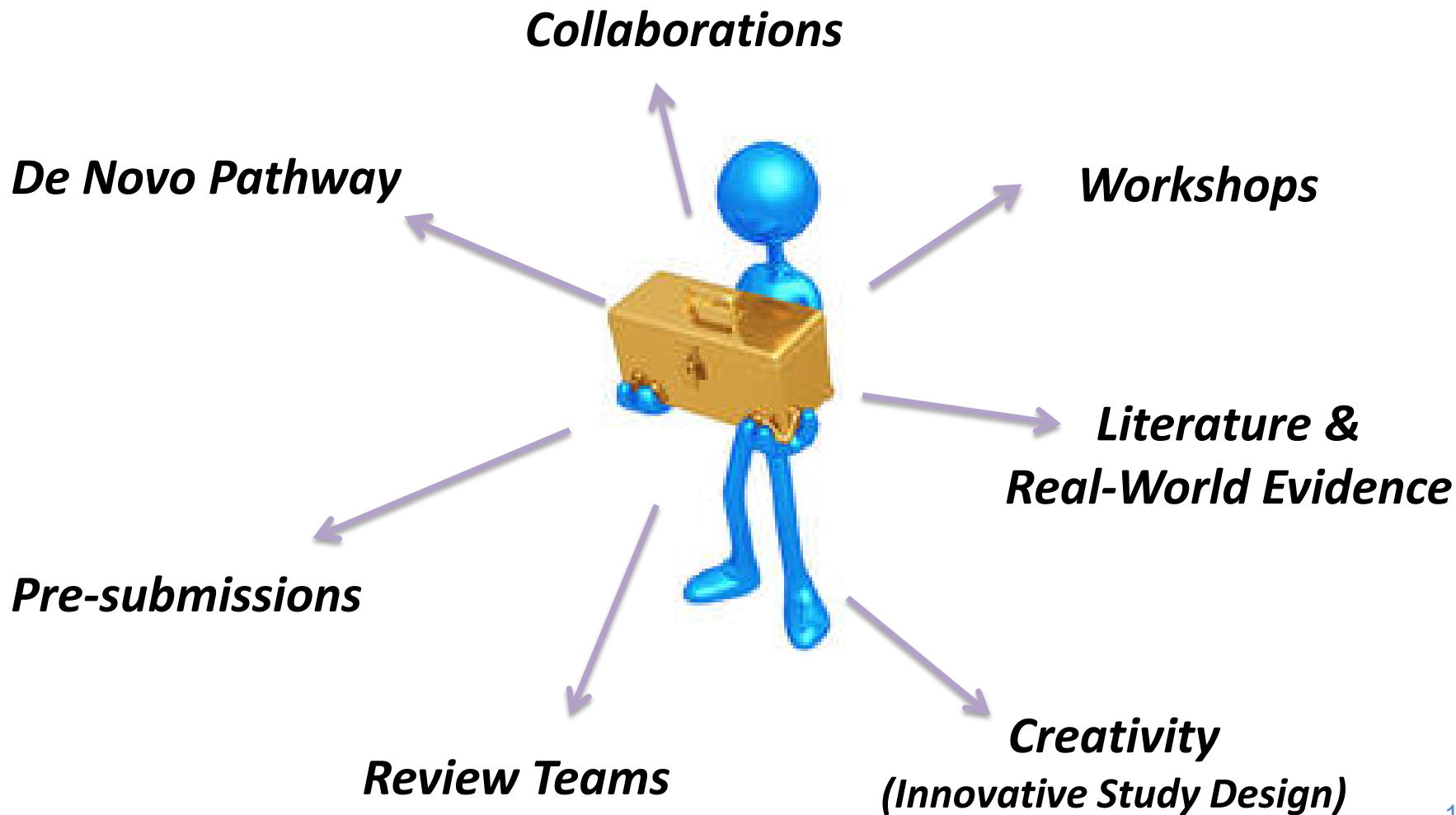


1 Submission



Team of Reviewers

Meeting the Challenge: Resources to Evaluate New Devices

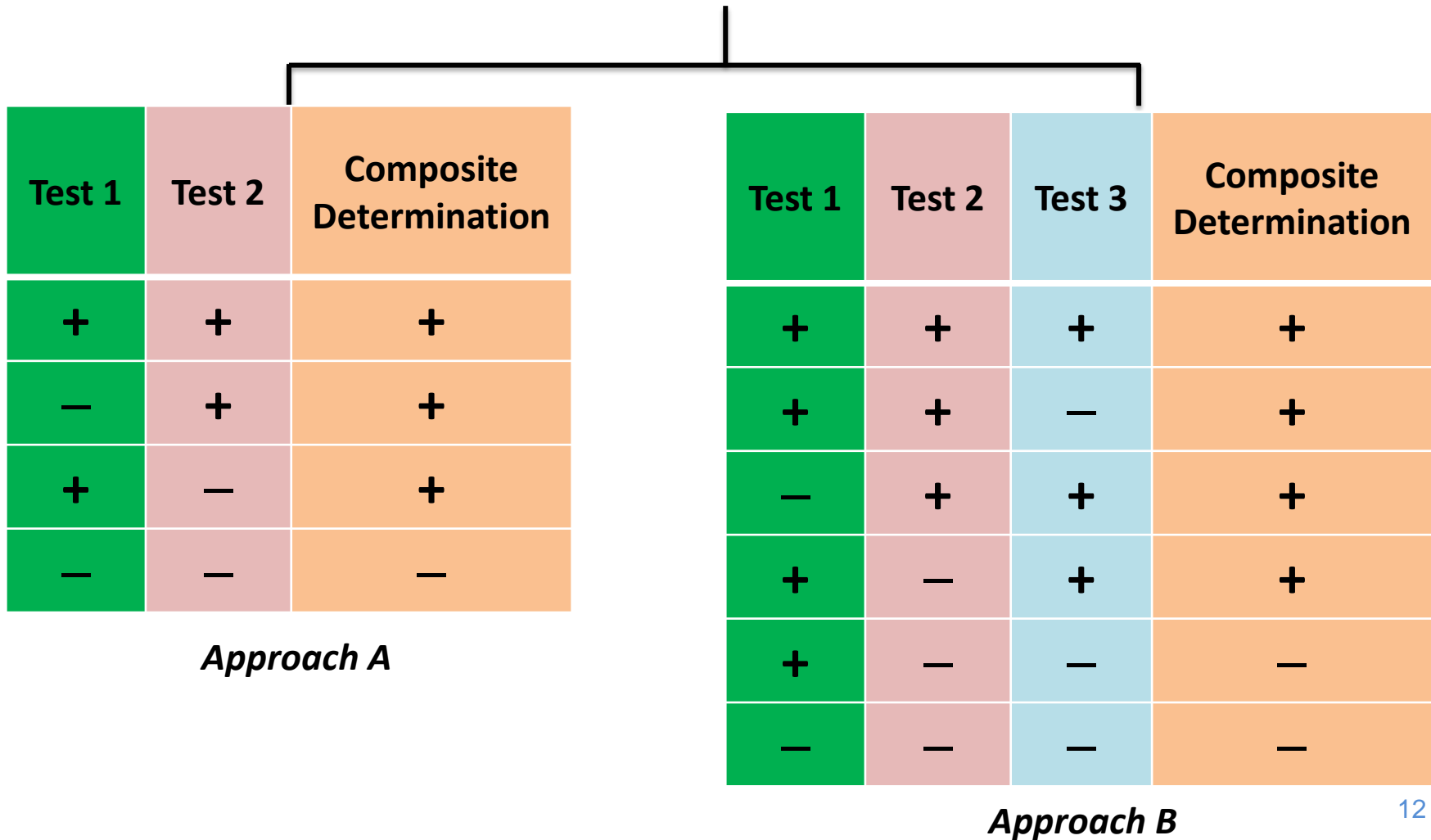


Meeting the Challenge

(Flexible Study Design)



Composite Reference Method (Hypothetical)



Summary

- The number and the scope of diagnostic devices for detection of AR markers continue to increase.
- Current technologies identifying AR markers have introduced new regulatory and scientific challenges, prompting a dialogue with stakeholders.
- We will continue to discuss issues pertaining to detecting, reporting, and interpreting AR markers later in the Afternoon Panel.

Thank You!