CDRH Preference Sensitive Areas Discussion: Diseases and Conditions where patient preference studies could be useful

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
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What is MDIC?

MDIC is a 501(c)(3) non-profit organization and is the first-ever public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit

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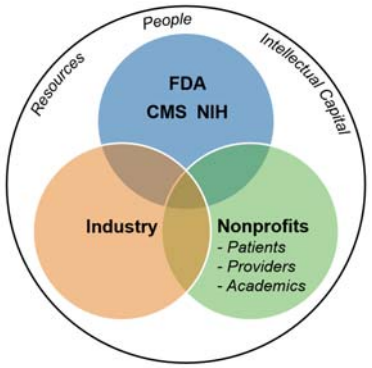

Align Resources

Accelerate Progress

Achieve Results

WORKING COOPERATIVELY
to re-engineer pre-competitive technology innovation

REDUCING TIME
and resources needed for new technology development, assessment, and review

HELPING PATIENTS
gain access to new medical technologies sooner

MDIC HIGHLIGHTS

65 participating member organizations

Leading resource on issues important to the Medtech innovation ecosystem

6 Projects have been initiated

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Congressional testimony on modernizing clinical trials

Over $35m funding from grants and contracts for Program initiatives

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MDIC Patient Preference Framework

Framework for Incorporating Patient Centered Benefit Risk Assessment into Regulatory Submissions

- Resource for CDRH, MDIC members, and industry on when and how to collect patient preference information for incorporation into the regulatory process
- Incorporates Catalog of Methods as appendix

Published in 2015, the Framework is the collaborative effort of industry, CDRH and patient preference experts

- An initial thought piece in an emerging area
- To be updated as industry, FDA, and patient groups gain experience with collecting/using patient preference information

http://mdic.org/spi/pcbr-framework-report-release/framework-report/

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The Value of Patient Preference Information

- Identify benefits and harms most important to patients
- Frame the benefit-risk issues and tradeoffs from the patient perspective
- Identify whether there are subgroups of patients that would choose to use the technology over other alternatives
- Support quantitative benefit-risk modeling

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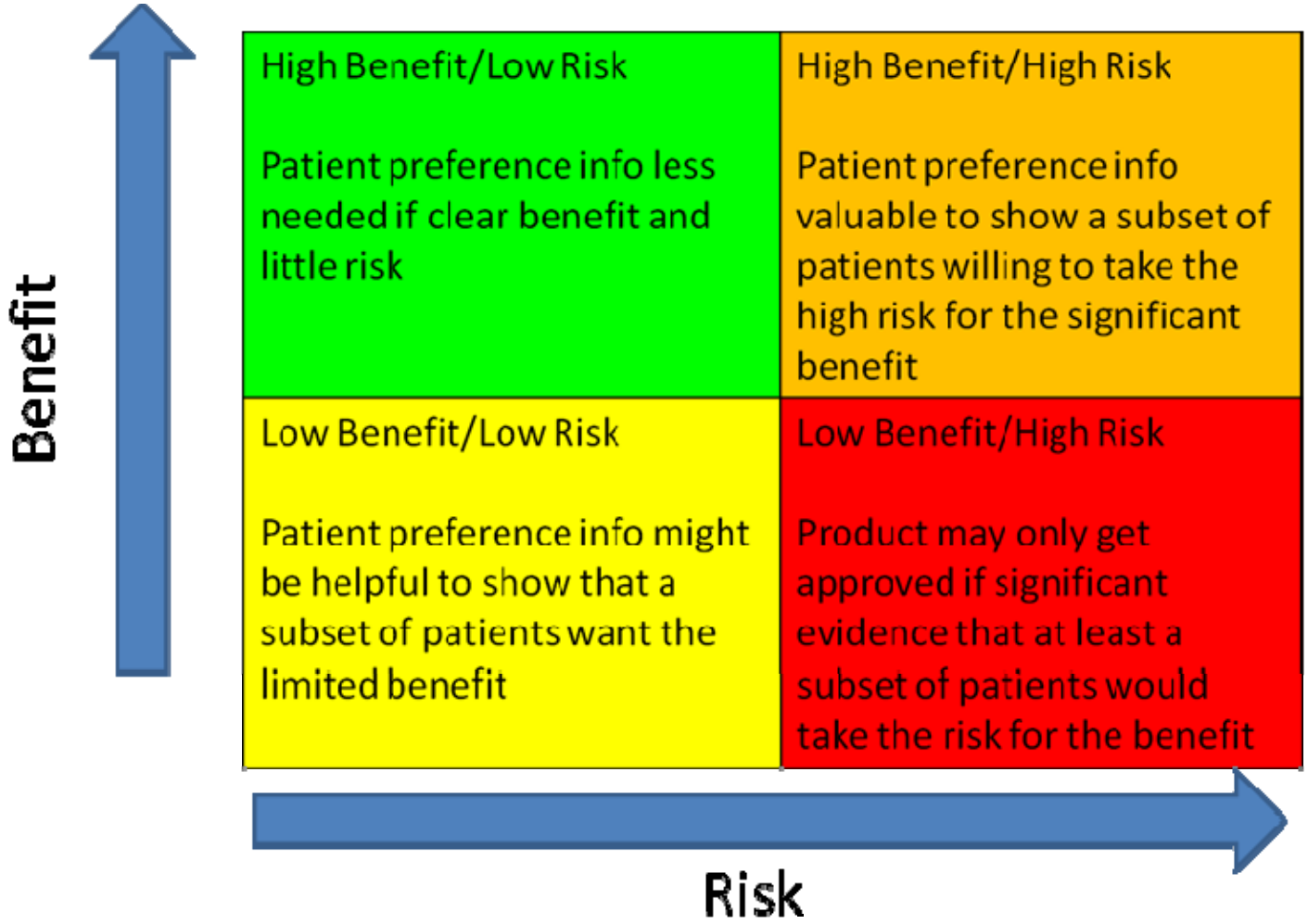
The value of patient preference information as a function of benefit and risk



Identifying preference sensitive areas

- Patients as stakeholders
  - Examples: Patient preference or risk tolerance different from other stakeholders; heterogeneity in patient preference
- Benefit-risk tradeoffs
  - Examples: Marginal benefit-risk scenarios
- Regulatory novelty
  - Example: Familiarity with the use of a particular technology

- See Section III of the MDIC Framework report (http://mdic.org/spi/pcbr-framework-report-release/framework-report/)

Areas that may be less preference sensitive

- When the patient is not a major stakeholder or decision-maker
- When the disease state/ technology are generally understood by sponsors and FDA staff and there is significant regulatory precedent for approval
- When the treatment is clearly superior to existing therapies with no tradeoffs in risk
- When the treatment meets an unmet medical need with poor outcomes such that the risk of treatment will not be greater than the risks of the untreated disease

- See Section III of the MDIC Framework report (http://mdic.org/spi/pcbr-framework-report-release/framework-report/)

Considerations for Patient Preference

- There is not a “cookbook” or algorithmic approach to identifying preference sensitive areas
- There are factors that characterize situations where patient preference information could be useful, in particular, in the context of regulatory benefit-risk assessments
- Let’s not limit ourselves to the regulatory considerations. Patient preferences can provide valuable insight across the medical device development lifecycle

Patient Preference Information Resources

http://mdic.org/spi/pcbr-framework-report-release/framework-overview/

For more information, visit: http://mdic.org/SPI/resources

Upcoming and archive webinars: http://mdic.org/mdicx