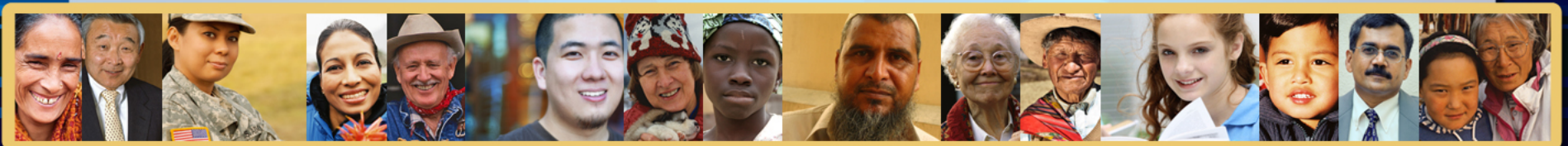


MAPPs: New Tools for Decision-Making
April 14, 2015

NEWDIGS: New Drug Development ParadIGmS



Applying MIT systems expertise to transform healthcare innovation

The NEWDIGS “Scenario Design” Methodology for Case-Based Collaborative Learning

Scenario Design Methodology

Asset Nominations and Fit Assessment



Design Session Preparation



Scenario Design Session



Consolidation & Summary

Numerous proprietary assets reviewed since 2011:

- 14 assets nominated by 9 companies
- 13 assets evaluated in scenario design sessions

Publications focused on:

- Overview of AL (multi-stakeholder co-author team)
- Modeling of stakeholder metrics in AL
- A (hypothetical) case study of AL
- Legal foundations of AL
- In-depth description of scenario design methodology
- Alignment of regulator/payer perspectives in AL
- AL in TB drug/regimen development
- Global update/accelerated regulator & payer pathways
- From adaptive licensing to adaptive pathways

EMA Pilot Project on AL:

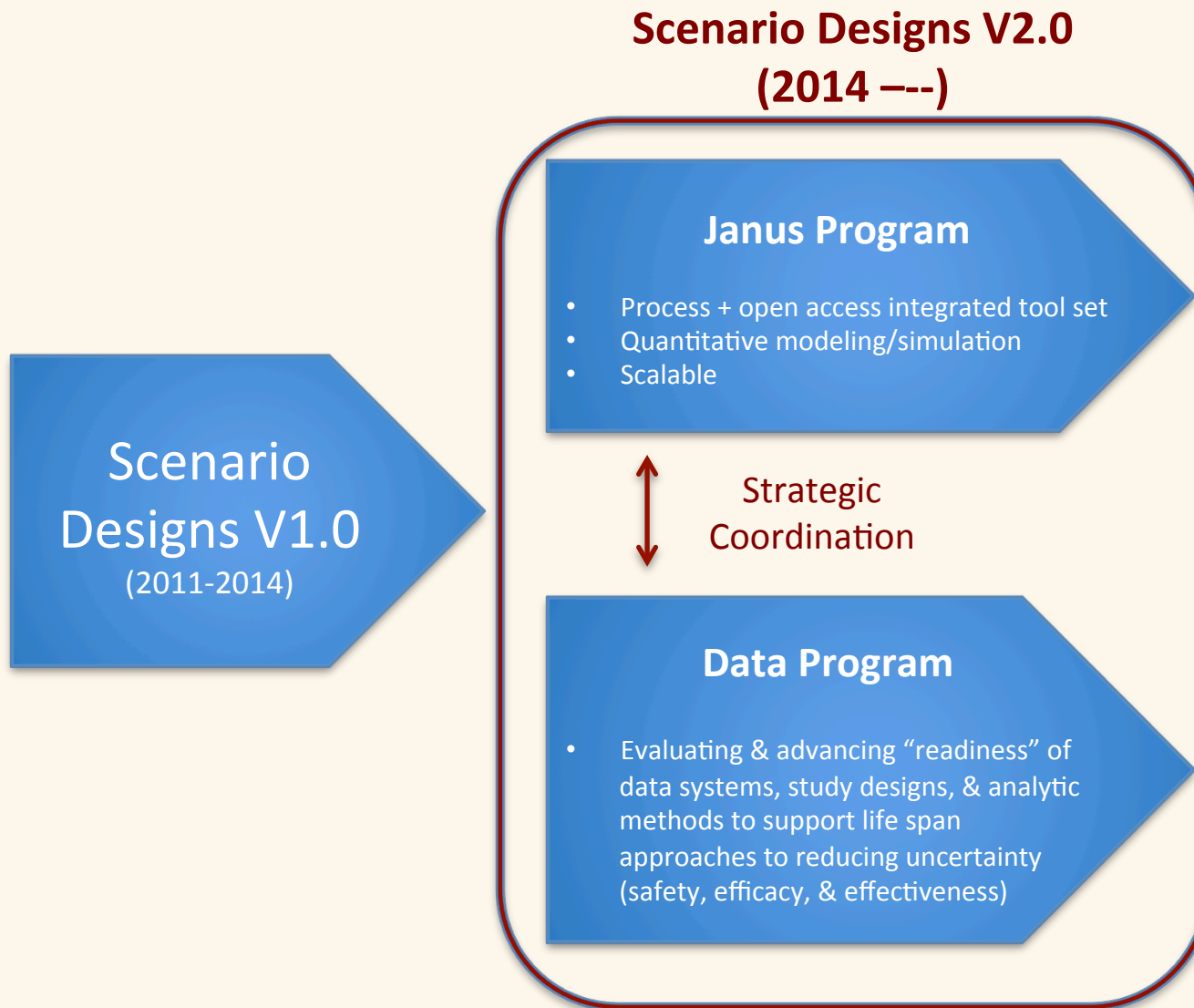
“In March 2014, the EMA began inviting companies to participate in a pilot project on adaptive licensing, and published a framework to guide discussions on individual pilot studies.

*... The pilot project builds on earlier work with the Massachusetts Institute of Technology's Center for Biomedical Innovation (CBI) to investigate the feasibility of this approach.” **

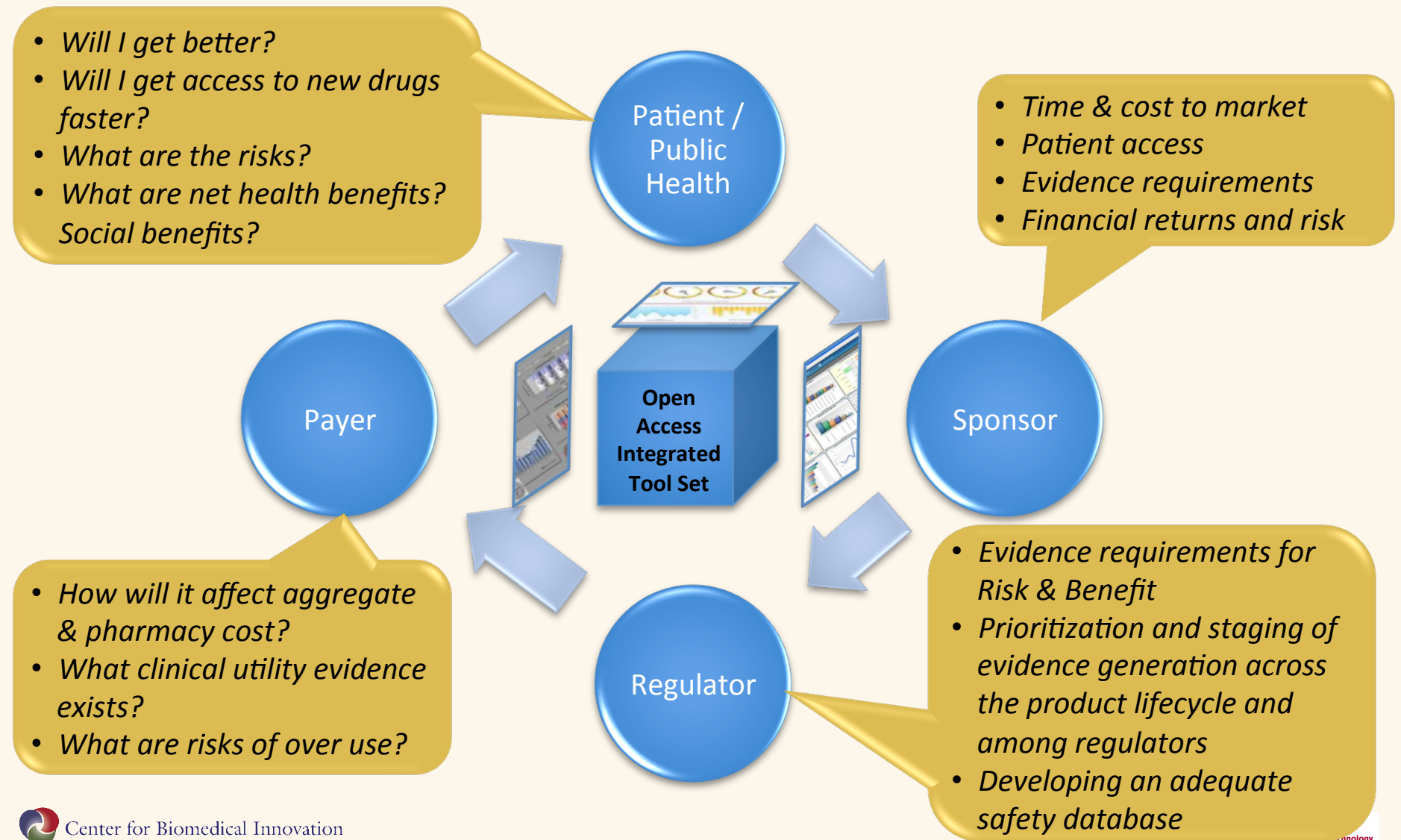
* www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp&mid=WC0b01ac05807d58ce#non



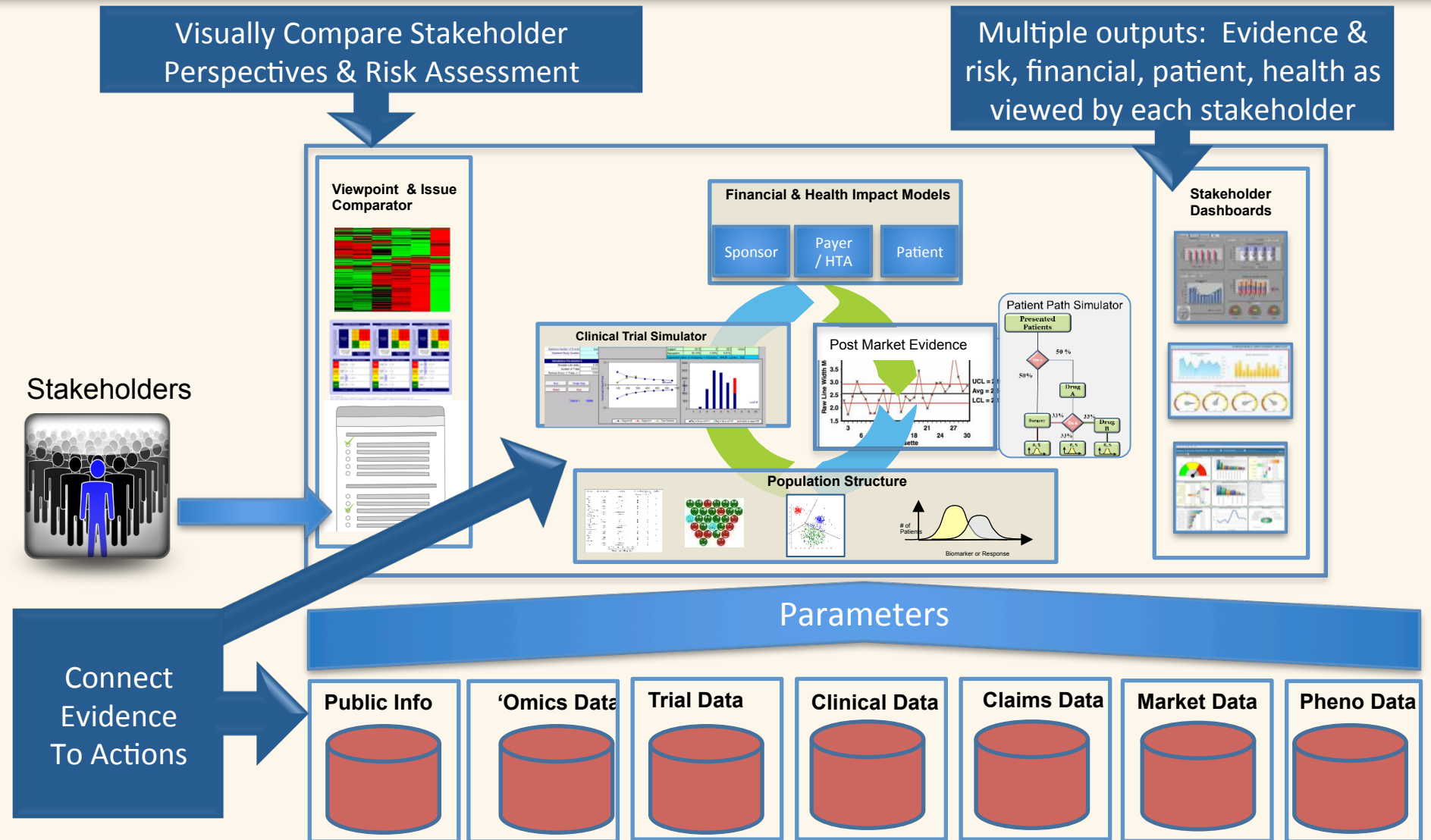
Scenario Designs V2.0: Enabling the Implementation of MAPPs



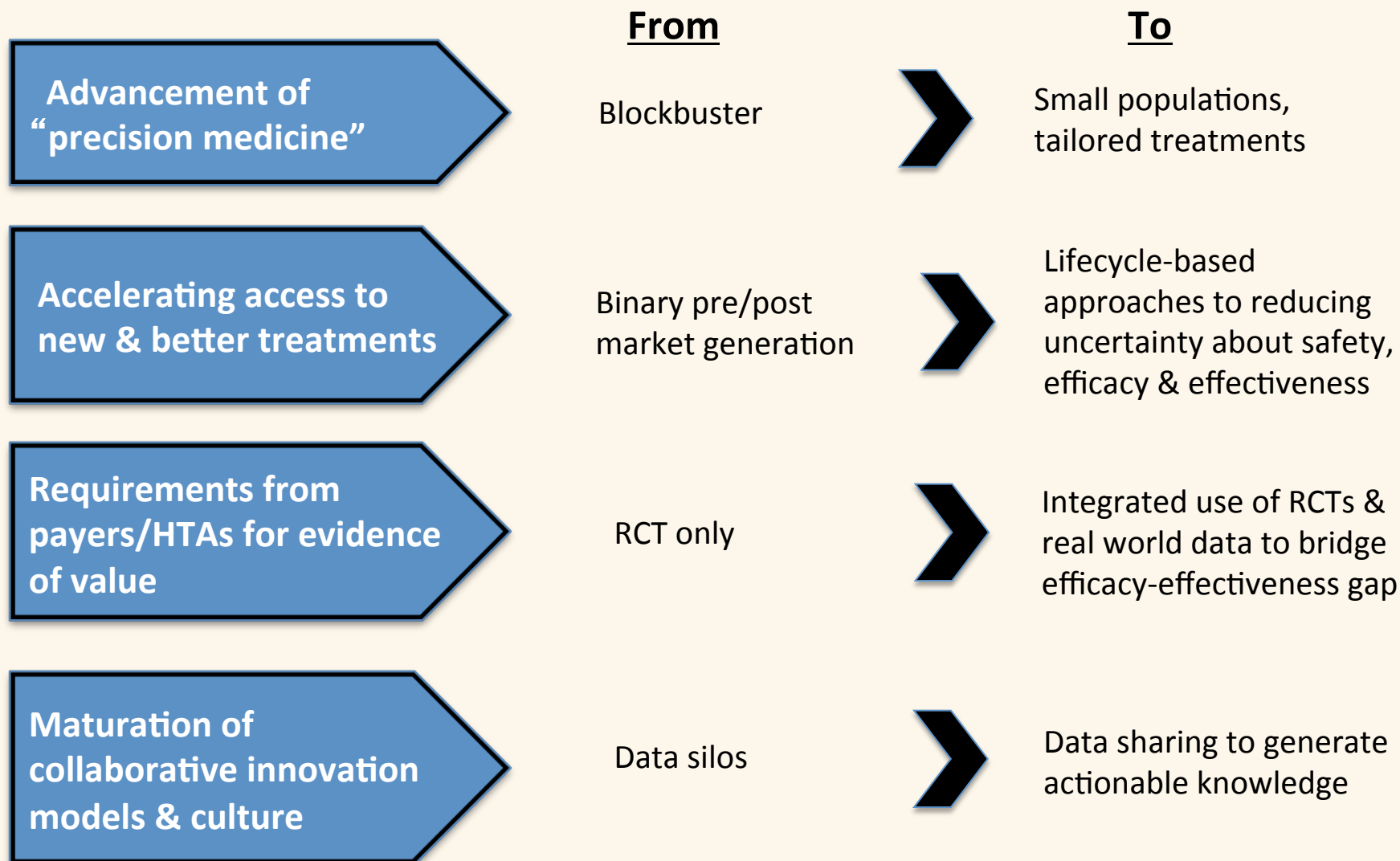
Janus Program: Integrates Major Viewpoints Across Life Span to Explore Meaningful Impact for all Stakeholders



Janus Program: Quantified, Connected Stories... Supported by Intuitive Visualization Tools... Designed to Foster Creative Consensus



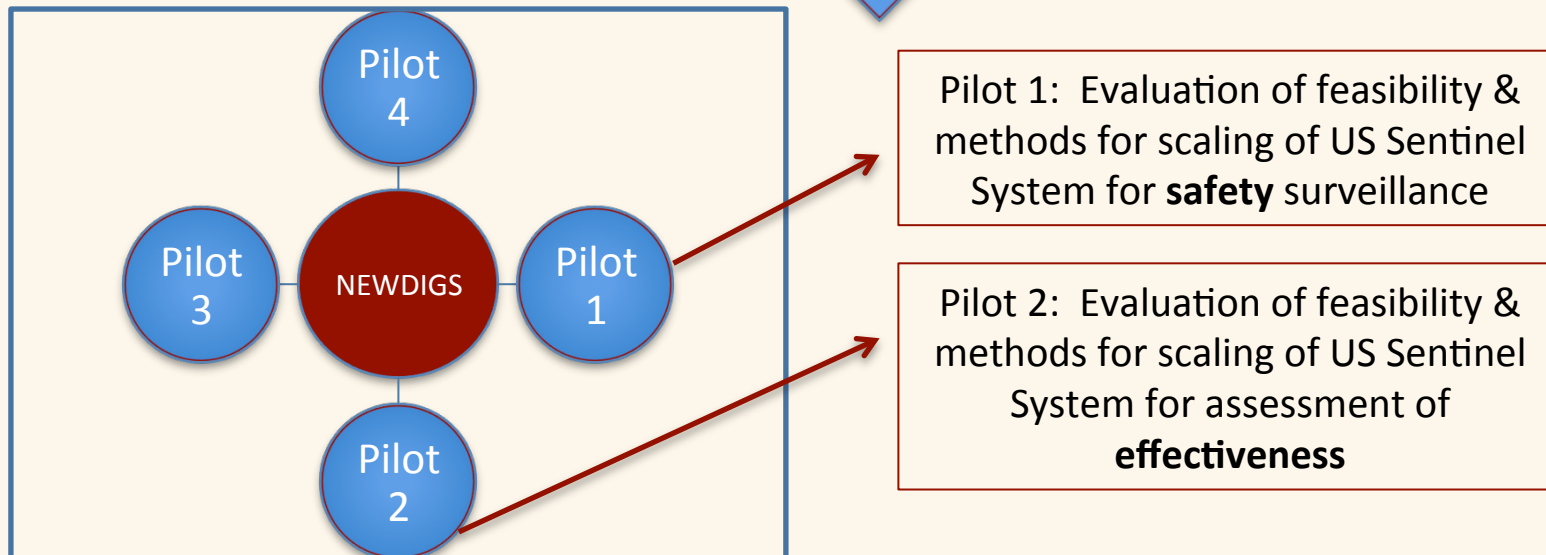
NEWDIGS Data Program Focuses on Convergent Change Drivers & Their Implications for the Disruptive Advancement of Health Data Access, Use, & Value



Sample (Hypothetical) Activity in NEWDIGS Data Program

Issue Identified: As innovation increasingly targets small sub-populations of patients, there will be an unprecedented need for international cooperation in the design & use of data systems in order to identify adequate numbers of patients to safely accelerate access & optimize value.

Scenario Design Session focused on uncertainty reduction/management plan for Initial Authorization phase of a targeted therapeutic involving multiple jurisdictions



Thank you.

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