



Green Park Collaborative
A partnership for innovation and effectiveness



FORUM
for Collaborative
RESEARCH

OAC
Obesity Action Coalition

Core Outcomes for NASH

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What is CMTP/GPC

Center for Medical Technology Policy (CMTP)

- Independent, non-profit 501(c)(3) organization
- Make health care more effective and affordable by improving the quality, relevance, and efficiency of clinical research
- Engage all relevant stakeholders:
 - Improve clinical research design
 - Improve research infrastructure
 - Promote evidence-based policy

Green Park Collaborative (GPC)

- Major program of CMTP
- Create shared understanding of evidence needs of ‘post-regulatory’ decision-makers
 - payers and HTA, patients, health systems
- Create greater transparency for innovators: what is needed to demonstrate effectiveness and value
- Multi-stakeholder platform for ‘reimbursement science’

“Reimbursement science”

“**Regulatory** Science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.”

“**Reimbursement** Science is the science of developing new tools, standards, and approaches to assess the **comparative effectiveness and value of products covered by public and private payers.**”

Value: Basic Definition

Health outcomes achieved per
dollar spent

IOM 2006

Health outcomes are inherently
condition specific and multi-
dimensional

Michael Porter, NEJM, 2010

Value – A matter of perspective



*Patients have a unique perspective and will consider issues differently than regulators, manufacturers, scientists, clinicians, and payers.**



Slide from Mark Skinner

Core Outcome Sets

“An agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical research in specific areas of health or health care”

Definition from the COMET Initiative

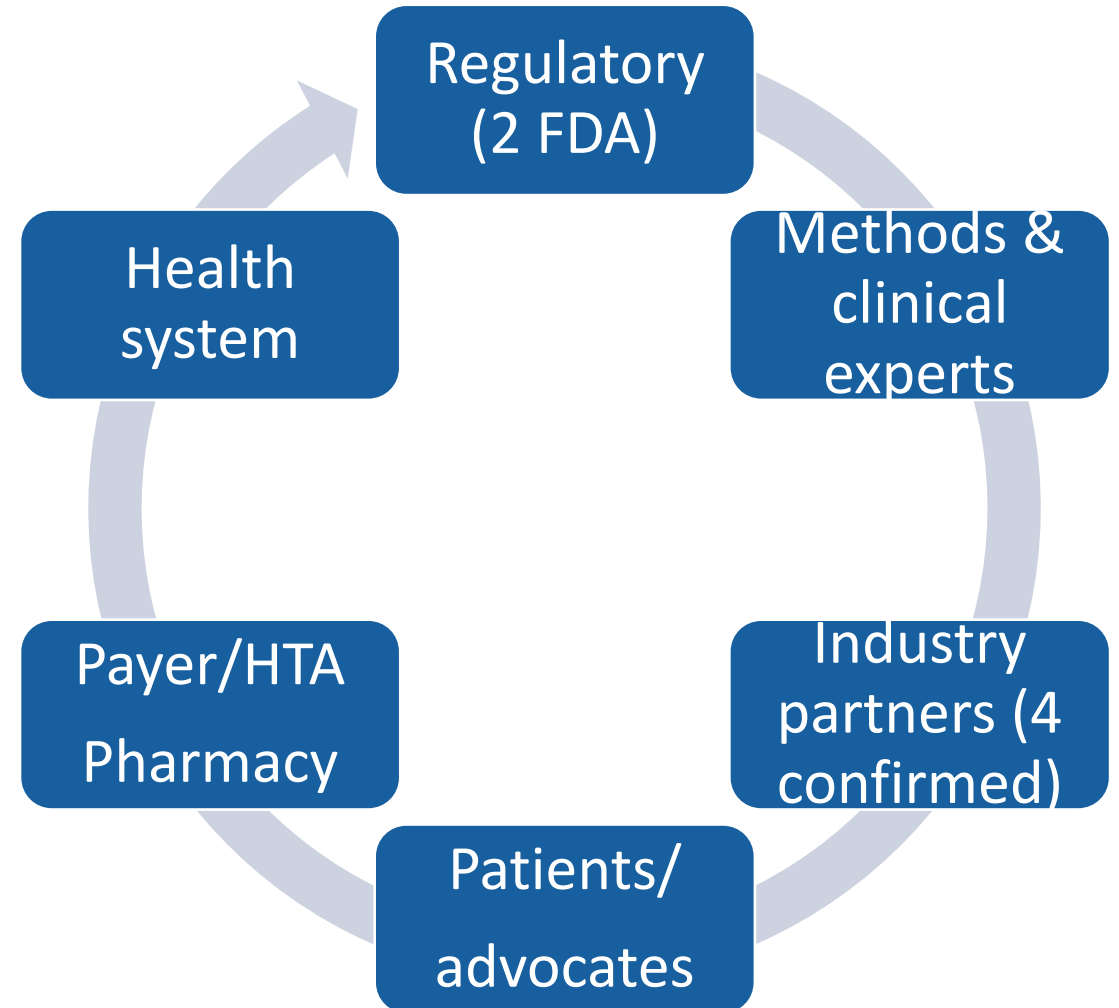
Why NASH? Why Now?

- Opportune time
 - many new products are in development
 - A potentially large patient population exists, with important public health issues
 - payers and HTA groups watching... have uncertainty about how to evaluate new treatments for NASH. They want to have this conversation.
- Best to have this conversation now, when adjustments can be made to clinical development plans

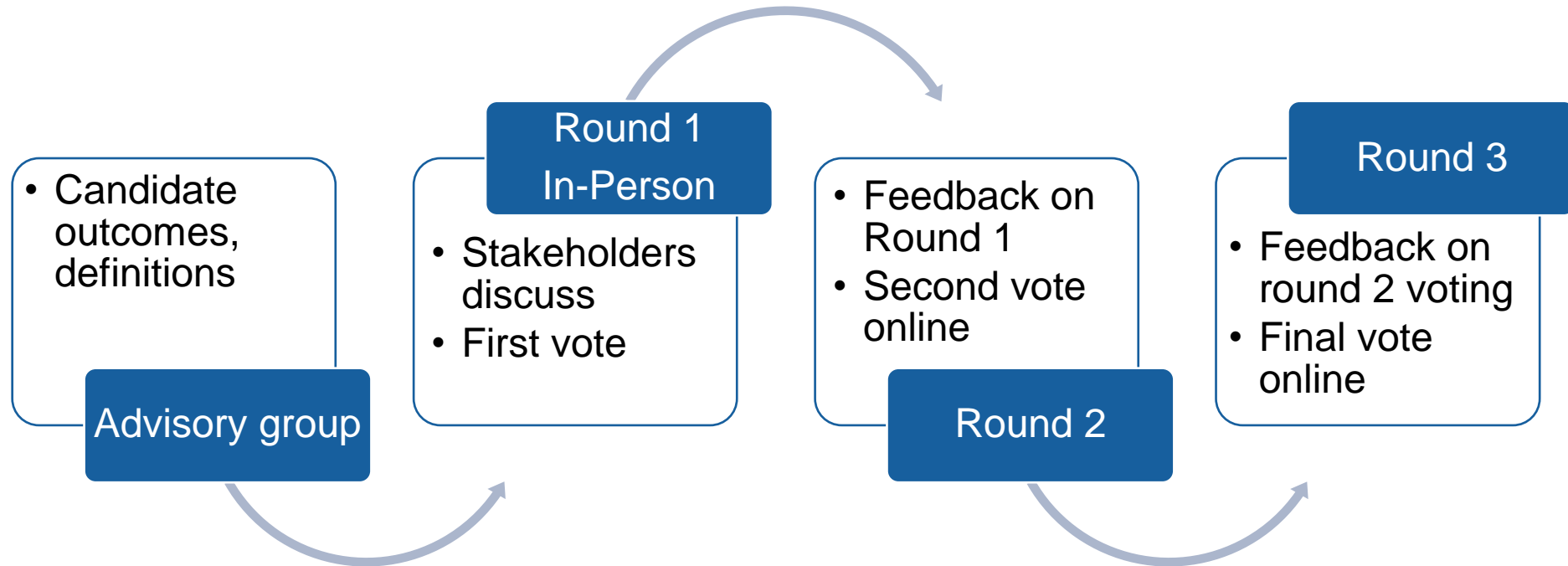
Multi-stakeholder

Partial List of Confirmed Payers/HTA

- Blue Cross Blue Shield Assn (BCBSA)
- Anthem
- Institute for Clinical and Economic Research (ICER)
- National Institute for Health and Care Excellence (NICE)
- United Health Group
- Michigan Medicaid
- Kaiser Permanente
- Geisinger



Delphi: Structured Consensus



Example: coreHEM



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders



BIOMARIN



Shire uniQure



Non-voting meeting participants



Genentech
A Member of the Roche Group



- Core outcome set for late phase gene therapy trials in hemophilia
- Completed rapidly (9 months)
- Participating companies committed to using core set; some have amended previously submitted protocols
- 12 participating payer/HTA groups from US & international
- Negotiating payer/HTA statement to acknowledge participation, encourage use of outcomes by companies

For more information



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Please catch me on a break during the meeting!