

**Patient Reported Outcomes –
Useful for Whom ?
*Industry's Perspective***

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AGENDA

- Why PROs ?
 - Applications of PROs in Drug Development
 - US Healthcare Reform – Enhanced Value of PROs
 - Key Takeaways
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Patient Perspective is Increasingly Valued....and Expected!

Importance of including the patient's perspective in drug development is increasingly recognized

Significance of including the patient's perspective has risen from multiple perspectives

Guidance: EMEA Reflection Paper on Health Related Quality of Life (2005); FDA PRO Guidance (2009); FDA Draft Guidance for Industry: Qualification Process for Drug Development Tools (2010); EMA DDT in draft (2012)

Critical-Path Institute's PRO Consortium (public/private partnership) developing new PRO tools (formed 2008) for use as endpoints making regulatory claims

Patient Centered Outcomes Research Initiative (PCORI)– expects patient involvement in research, and meaningful outcomes to be measured and communicated in meaningful way – to the patient

National Quality Forum – focusing on how to apply PROs to performance measures, for potential evaluation of providers, etc.

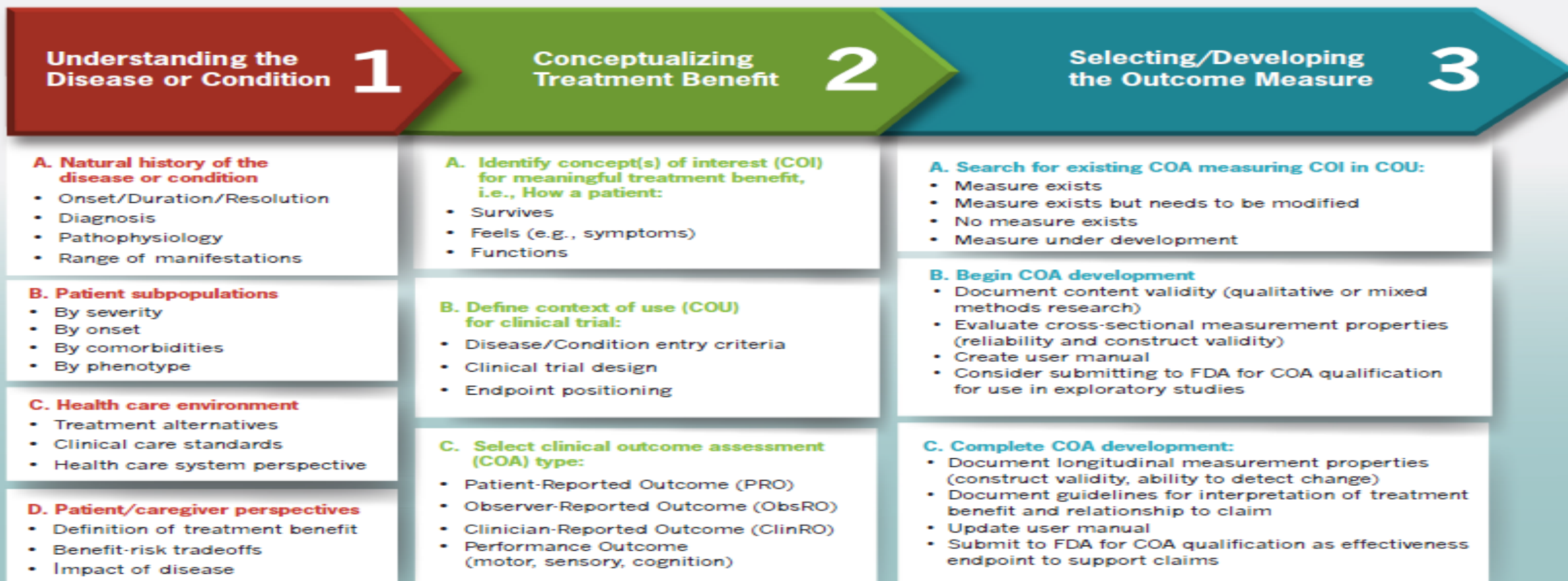
PDUFA FDA Patient Focused Drug Development Initiative – actively incorporating patient perspective into what diseases should be of focus

Health Care Decision Makers – using PROs in interventional /disease management programs as well as tools used to assess patient outcomes at the point of care. Providers are also recognizing incorporation of Patient Perspective as a **source of competitive advantage**



FDA Roadmap to Patient-Focused Outcomes Measurement

Roadmap to **PATIENT-FOCUSED OUTCOME MEASUREMENT** in Clinical Trials



Application of PROs in Drug Development

CONCEPT ELICITATION

- Disease and treatment impact
- Definition of treatment benefit
- Benefit-risk tradeoffs

EXIT INTERVIEWS

- Explore indications
- Understand benefits vs. risks
- Substantiate or complement other PRO measures
- Highlight potential issues for adherence to treatment
- Identify subpopulations with greatest response or patients unlikely to benefit from the treatment

PATIENT PREFERENCE-UTILITIES

- Complementary to clinical and safety data on benefits and risks of new treatments
- Used in economic evaluation to inform resource allocation decisions

CONJOINT ANALYSIS

- Used to understand patient preferences
 - Benefit-risk tradeoffs
 - Inform drug development decision-making
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Why Should PROs be Important to HTAs/ Payers ?

- **Basis for indication** – primary or co-primary endpoint – in certain symptomatic diseases
- **Differentiate and add value (e.g. key secondary endpoint in labeling)**
 - Demonstrate meaning of primary endpoint
- **Complementary information**, to support treatment benefits even if not in the label (e.g. publication, global value dossiers, HTA submissions)



Our Focus

US Healthcare Reform: Enhanced Value of PROs

Changes in US Healthcare (HC) system have lead to transformation in delivery systems with focus on:

- Decreasing rising HC costs
- Increasing patient satisfaction
- Improving patient outcomes

Implication of these changes:

- Need for simple, easy to use patient tools -
 - Disease awareness
 - Clinical practice tools that can be administered at the point of care

Challenges:

- Minimal evidence demonstrating improved patient outcomes results in reduction in HC costs
- Incorporation into EHRs

Opportunities and Challenges

Future Trends will Continue to Enhance the Value of PROs



TECHNOLOGY:
Mobile Computing
Smartphones/Tablets
Apps
Social Media
mHealth
eHealth Records
Big Data Analytics



CLINICAL TRIALS:
Sensor technologies
Real-time tracking
Remote labs
Drug adherence
Patient selection/retention
Personalised medicine
Global/remote sites
The Digital Pill



HEALTHCARE:
Economics of healthcare
Pharma industry consolidation
R&D attrition and productivity
Virtual HCPs
Local clinics (non-MD)
Developing economies

Key Takeaways



- **PROs can show important differences in efficacy/tolerability to support access for medicines**
 - **Likely to be increasingly important in the future** - PROs in drug development, disease awareness tools, clinical practice tools
 - **Implications for pharmaceutical industry**
 - Develop a PRO strategy early and proactively
 - Closely review in which TAs PROs make a difference
 - Monitor what and how PROs are being used (e.g. as performance measures, clinical practice tools, labeling claims, etc)
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Thank you for your attention!

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