

1

HEAR updates from FDA on:

- The Qualification of Drug Development Tools program mandated by 21st Century Cures Act
- The use of Clinical Outcome Assessments in oncology clinical trials
- How FDA's Patient-Focused Drug Development is impacting endpoint selection, design, and validation

2

DISCUSS the needs and requirements of critical stakeholders for study endpoint data — patients, regulatory agencies, clinicians, and payers

3

OBTAIN updates from the C-Path PRO Consortium

4

LEARN about DIA's Study Endpoints Community and how to propose and join Scientific Working Groups

5

NETWORK with experts involved in endpoint development and clinical outcomes

RELEVANT RESOURCES

FDA

Drug Development Tool Programs and Initiatives



Patient-Focused Drug Development



Clinical Outcome Assessment Qualification Program

EMA

Qualification of Novel Methodologies for Medicine Development

Other

DIA Study Endpoints Community



EUPATI Patient Reported Outcomes (PRO) Assessments



IMI PROactive Project



C-Path PRO Consortium



C-Path ePRO Consortium



CTTI Novel Endpoints Project

Advancing the Science of Study Endpoints
September 20-21

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