

Setting the Scene

Breakout session D: Validation of digital endpoints

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Big Data Steering Group workplan

Data discoverability

Publish RWD & metadata
catalogue good practice guide

Review utility of eHealth data

Launch EMA-HMA catalogues of
data sources & non-
interventional studies

Stakeholder engagement to populate catalogues, incl. with patients organisations

Consult on reflection paper on Patient Experience data

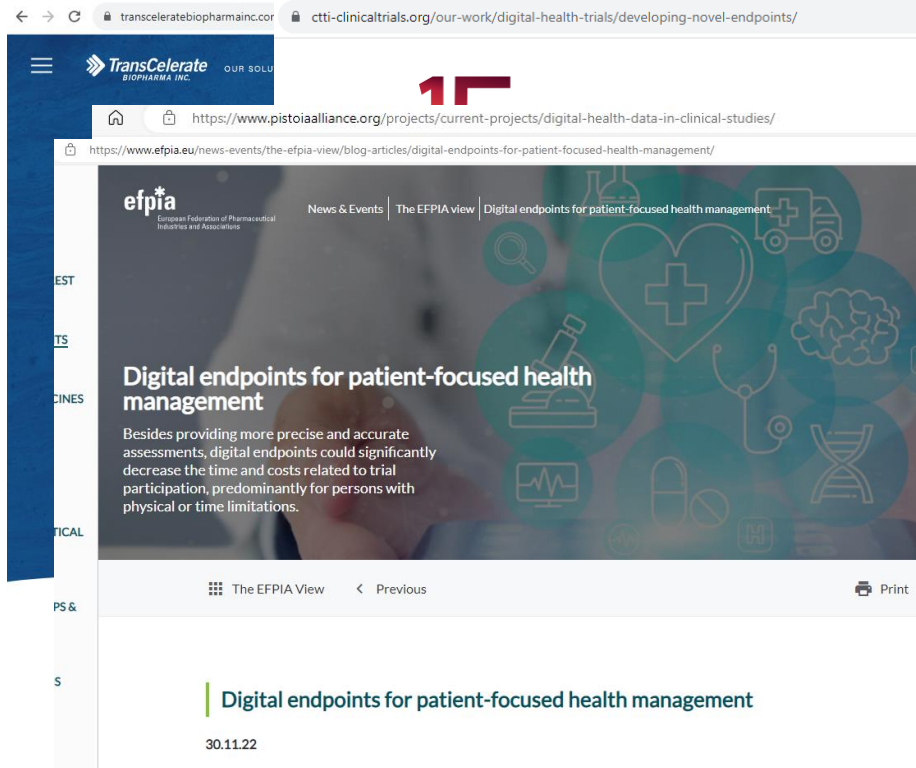
Engage with ERNs/registries

Review RWD & metadata catalogues'
maintenance and extension process

Review utility of social media

Extend RWD and metadata
catalogues to veterinary
data sources (V)

Industry collaboration



ISPOR Conferences

The Digital Endpoints Ecosystem and Protocols (DEEP) Initiative



ACT EU multi-stakeholder methodology workshop

SCOPE 2023

17 presentations/sessions on Digital Measurements vs 16 for biomarker (n=307)

Precompetitive Development of Digital Measures in Parkinson's Disease

Novel AI-Enabled Sensors for Quantifying Itch By Measuring Scratch

Leveraging Clinical and Real-World Studies to Develop and Validate Nocturnal Scratch and Sleep Measurements

Validation and Application of the Novel Digital Endpoints of Nocturnal Scratch and Sleep

The Value of Passive Data Collection: Tying Active Assessments to Passive Measurements in Clinical Research

LUNCHEON PRESENTATION: Reinventing the Six Minute Walk Test: A Novel Approach to Digital Measures

Scratching Detection Algorithm and Digital Endpoints Development for Atopic Dermatitis Patients

How to Improve Clinical Trial Data with Continuous Glucose Monitoring (CGM)

Considerations for Digital Endpoints: Digital biomarkers, sensors and PRO empowering clinical trials

SCOPE 2023 continued

Regulatory Update on Digital Endpoints

The Need for Novel Endpoints: Using Multimedia, Audio and Video to Capture Novel Digital Endpoints

PANEL DISCUSSION: Novel Evidence for Regulatory Decisions: The Key Factors for Success

Disruptive and Patient-Focused: Innovation to Meet Digital Endpoints

Remote Symptom Monitoring: Combining Active and Passive Digital Measures

MagnolAI - A Sensor Cloud for Connected Clinical Trials

The Anatomy of Connected Digital Health Platform

LUNCHEON PRESENTATION: Utilizing AI-Powered Technology for Patient Matching & Site Selection to Expedite Research to Patient's Doorsteps

Thank you
