W5 – Application of Gamification in Healthcare and Outcomes measurement: Improving treatment compliance and research engagement

MICHAEL ACQUADRO, JOHN HARRISON, JURRIAAN VAN RIJSWIJK

Discussion leaders

- Michaël Acquadro, PhD, Research Associate at Mapi, an ICON plc company, Lyon, France.

- John Harrison, PhD, PhD, Visiting Professor at Institute of Psychiatry, Psychology & Neuroscience, King’s College, London, UK; Principal Consultant at Metis Cognition Ltd., Kilmington Common, UK; Associate professor at Alzheimer Center, VU Medical Center, Amsterdam, The Netherlands.

- Jurriaan van Rijswijk, MSc, Founder and Chairman of Games for Health Europe Foundation, Eindhoven, The Netherlands.
Presentation overview

1. Introduction on regulatory aspects of Gamification (Acquadro)
2. Use of Gamification in Clinical Trials (Harrison)
3. Presentation of Gamification applied in health context (Van Rijswijk)
4. Gamifying an existing PRO (Van Rijswijk)
5. Discussion with the Panel

Introduction to Regulatory Aspects of Gamification

MICHAËL ACQUADRO
Regulatory aspects of Gamification
How common are smartphones in the world?

Some numbers from 2018:
- US: 77%
- France: 76%
- UK: 82%
- Germany: 78%
- Spain: 72%

Source: Newzoo 2018 Annual Market Report

Electronic Clinical Outcome Assessment (eCOA)

- FDA Guidance for Patient-Reported Outcome Measures (PRO) – Section F: Specific Concerns When Using Electronic PRO Instruments (December 2009)

- EMA Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials (June 2010)

- Change in practice for collecting data: more compliance, more reliable, more consistent, meets regulatory standards.

FDA permits marketing of mobile medical application for substance use disorder (SUD)  
*September 14, 2017*

- Pear Therapeutics: reSET application.
- FDA Clearance as a Computerized Behavioral Therapy device for psychiatric disorders: first time in the world.
- Used with outpatient therapy to treat alcohol, cocaine, marijuana and stimulant SUDs.

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Experimental Video Game hit its main goal in a pivotal clinical trial involving 348 ADHD children  
*December, 2017*

- Akili: AKL-T01 application.
- ADHD children and adolescents utilized AKL-T01 for 4 weeks, and showed statistically significant improvement on test measuring attention and screen for disorder.  
  (Change in the Attention Performance Index (API), an overall composite score, from the Test of Variables of Attention (TOVA 8))
- Seeking FDA clearance as the first prescription digital treatment for pediatric ADHD.
FDA draft guidance for Early Alzheimer’s Disease (AD)

February, 2018

- Guidance to assist sponsors in the clinical development of drugs for the treatment of sporadic AD before the onset of overt dementia.

- Challenge: detecting subtle abnormalities with sensitive neuropsychological measures.

- Current assessment tools used for overt dementia may not be suitable for early stage patients.

How many gamers in the US?

- A. 15%
- B. 30%
- C. 45%
- D. 60%

*Source: Entertainment Software Association, 2018*
How about the world?

Everyone is a gamer.

Use of Gamification in Clinical Trials

JOHN HARRISON
Themes – so why bother?

Selection (also compliance and retention)
...user acceptance?
...not just answers, but metadata too
...beyond questionnaires

Selection
Getting the right patients
Recruitment pressure
Screen failure
Bending the rules

User acceptance

Metadata

Not just what the study participant says, but also how they say it:

Speed of response

Prosody (issues of stress and intonation)

Things not dreamt of...
Beyond questionnaires

https://vimeo.com/105469094

Presentation of Gamification applied in health context

JURRIAAN VAN RIJSWIJK
Gamifying an existing PRO

JURRIAAN VAN RIJSWIJK
To start the demo please make sure your phone or laptop is connected to the internet.

For iphone:
Open your camera and keep it in front of the QR code. Click on the notification to open the browser.

For Android:
Scan the QR code with a QR code scanner or type the following URL:

https://default.questionr.nl/demo?qid=isper

Panel Discussion

MODERATOR: JOHN HARRISON