

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, M Sc, 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

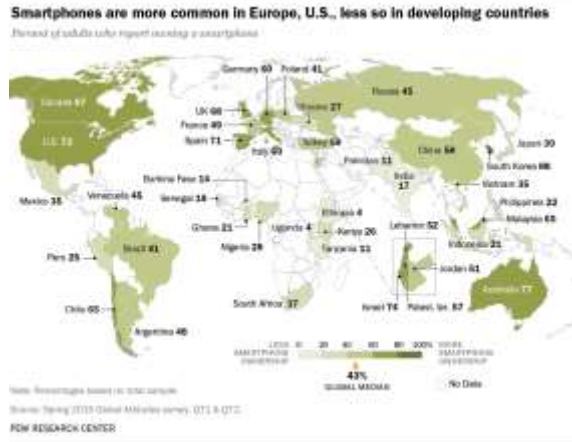


Introduction to Regulatory Aspects of Gamification

MICHAËL ACQUADRO



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.



Stone, A. A., Shiffman, S., Schwartz, J. E., Broderick, J. E., & Hufford, M. R. (2003). Patient compliance with paper and electronic diaries. *Controlled clinical trials, 24(2)*, 182-199.

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.



Figure 1 : The reSET device Status screen report



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.



Figure 2 : Screenshot from AKL-T01 game Akili's game designed to treat 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 %



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

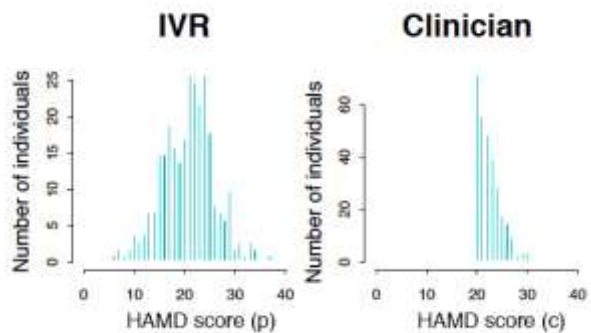
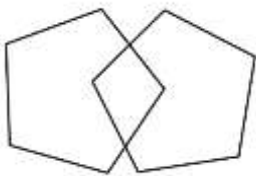
Selection

Getting the right patients

Recruitment pressure

Screen failure

Bending the rules



Byrom B & Mundt JC (2005) The value of computer-administered self-report data in central nervous system clinical trials. *Current Opinion in Drug Discovery & Development* 8(3):374-383

User acceptance

```
Welcome to
EEEEEE LL IIII ZZZZZZ AAAA
EE LL II ZZ AA AA
EEEE LL II III AAAAAA
EE LL II ZZ AA AA
EEEEEE LLLLLL IIII ZZZZZZ AA AA

Eliza is a sock Rogerian psychotherapist.
The original program was described by Joseph Weizenbaum in 1966.
This implementation by Robert Landsteiner 2005.

ELIZA: Is something troubling you ?
YOU: Men are all alike.
ELIZA: What is the connection, do you suppose ?
YOU: They're always buggind us about something or other.
ELIZA: Can you think of a specific example ?
YOU: Well, my boyfriend made me come here.
ELIZA: Is it important to you that your boyfriend made you come here ?
YOU: He says I'm depressed much of the time.
ELIZA: I am sorry to hear that you are depressed.
YOU: It's true. I am unhappy.
ELIZA: Can you explain what made you unhappy ?
YOU: 
```

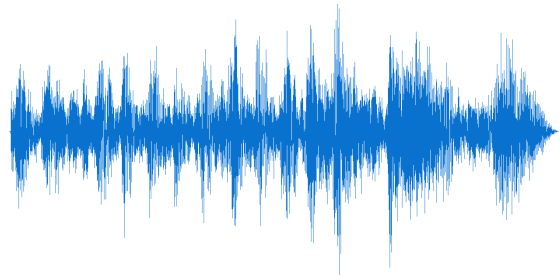
Metadata

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

Play

how it shapes the brain,
opens the imagination,
and invigorates the soul

To continue with this
presentation in Prezi
click on the picture.
(internet required)



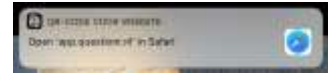
Gamifying an existing PRO

JURRIAN 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 an QR code scanner or type the following URL:

<https://default.questionr.nl/demo?qid=ispor>

Panel Discussion

MODERATOR: JOHN HARRISON