



Games as Medicine

FDA Clearance Methods

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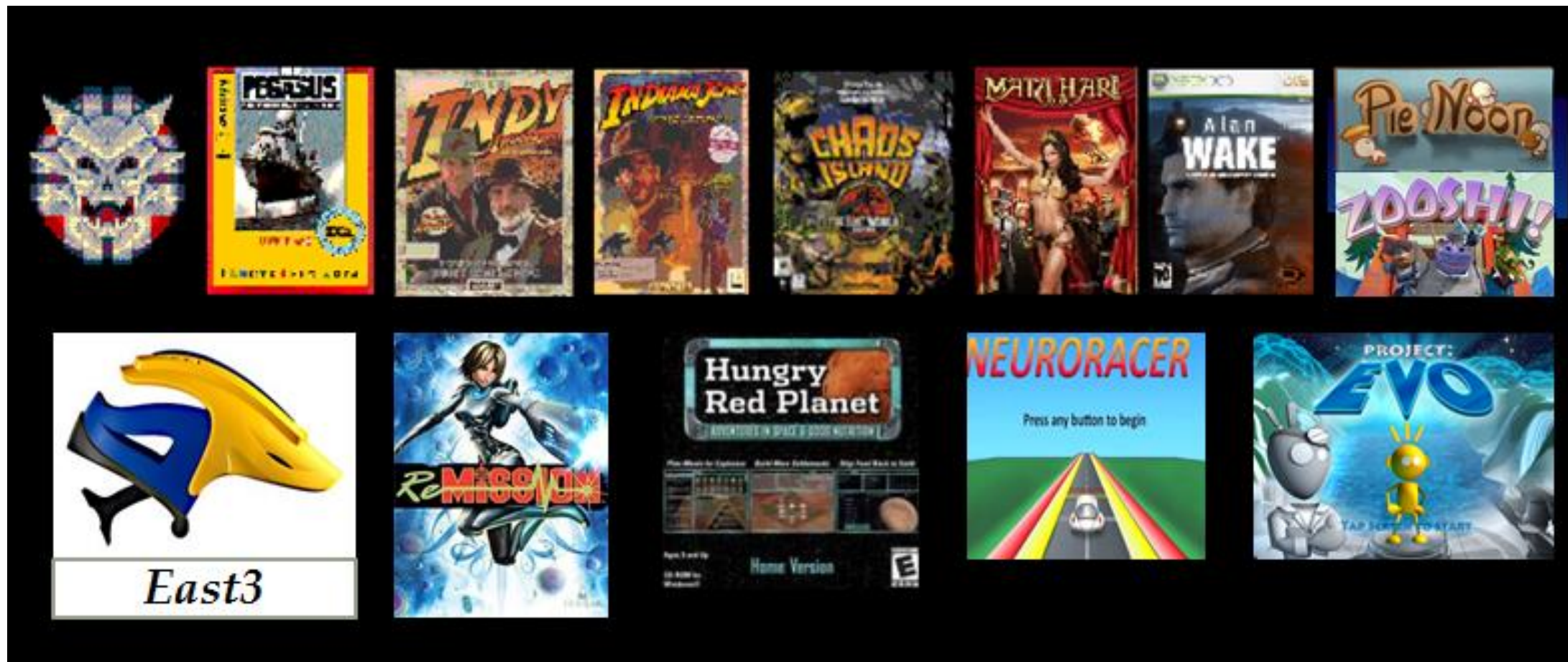
Quick survey to calibrate the talk

- Anyone primarily from health/medical?
- Anyone shipped games for health or other game/medical crossover software?
- How many game devs just curious about health games?





My Background





Caveats

- Damn it Jim, I'm a game designer, not a doctor!
- 25 minute overview of complex subject
- Full disclosure - ties to several companies discussed, no compensation for this talk, just deeper knowledge of companies I work with





What I'll Cover

- Context of Games for Health, bit of history
- New factor of FDA clearance, what it implies
- Deeper dive into how it can be addressed
- Advantages/disadvantages of going for FDA clearance





Why Games and Health?





Why Games and Health?

1. Helping people

Picture from Stanford C.H. -
Dr. Sam Rodriguez's work
(Google **Rodriguez pain VR**)





Why Games and Health?

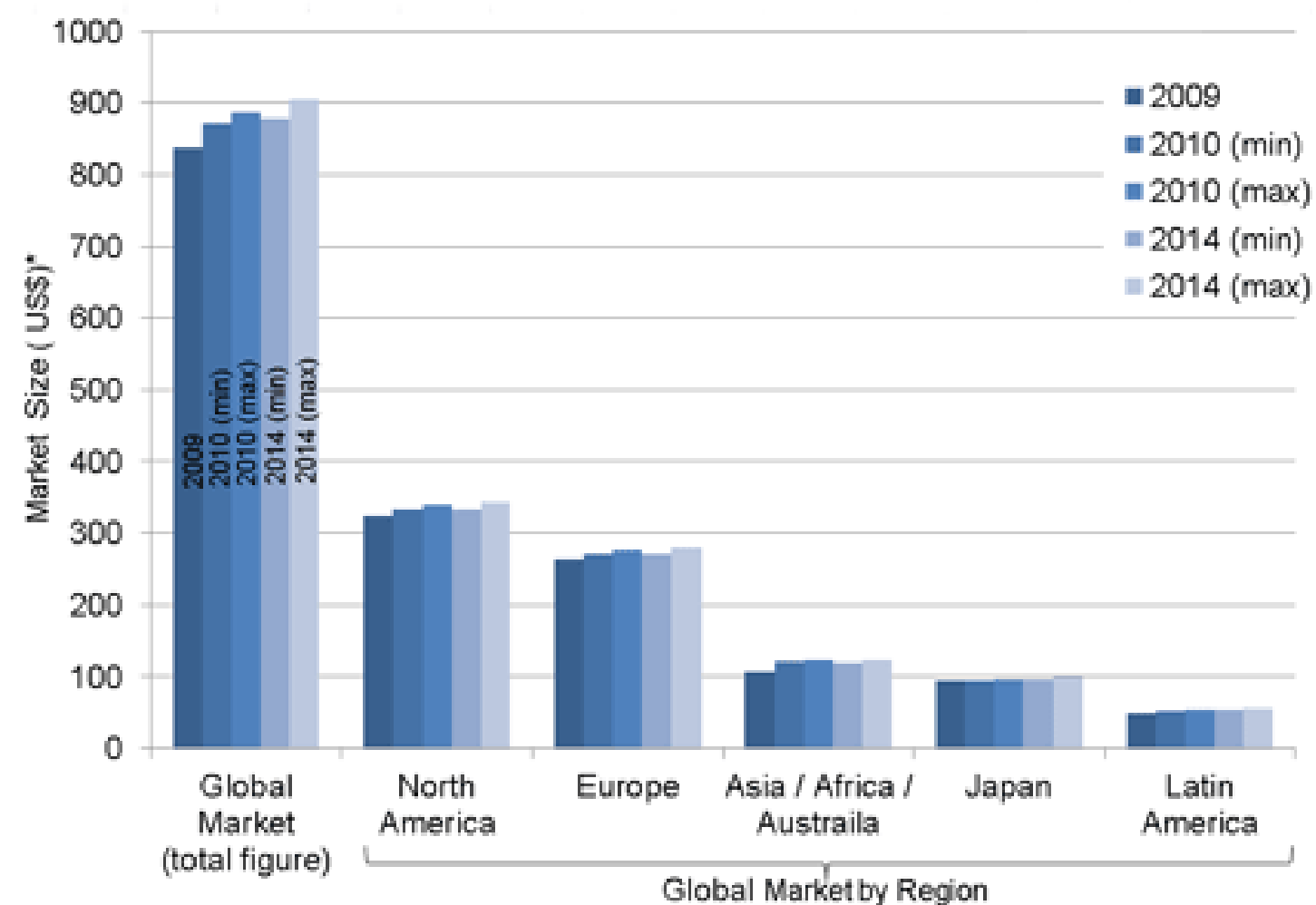
2. It's challenging, exciting, more diverse than standard games





Why Games and Health?

3. FDA clearance = big market





So what's the catch?





There have been mis-steps

- Brain training
- Wii Fit (+U)
- Lumosity fine





Some bright spots

- ReMission from Hopelab
- \$3.75M study
- Randomized controlled study showed significant adherence





FDA clearance is gold standard

- Need to prove efficacy, safety for this
- Working on SaMD - Software as Med Dev.
- Biggest single world market, drives others
- Necessary for prescription, helps with insurance reimbursement
- BUT - it's expensive, time consuming





FDA Device Classifications

State of health care situation or condition	Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
Critical	IV	III	II
Serious	III	II	I
Non-Serious	II	I	I





FDA definition of serious disease

. . . a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.





MindMaze Pro

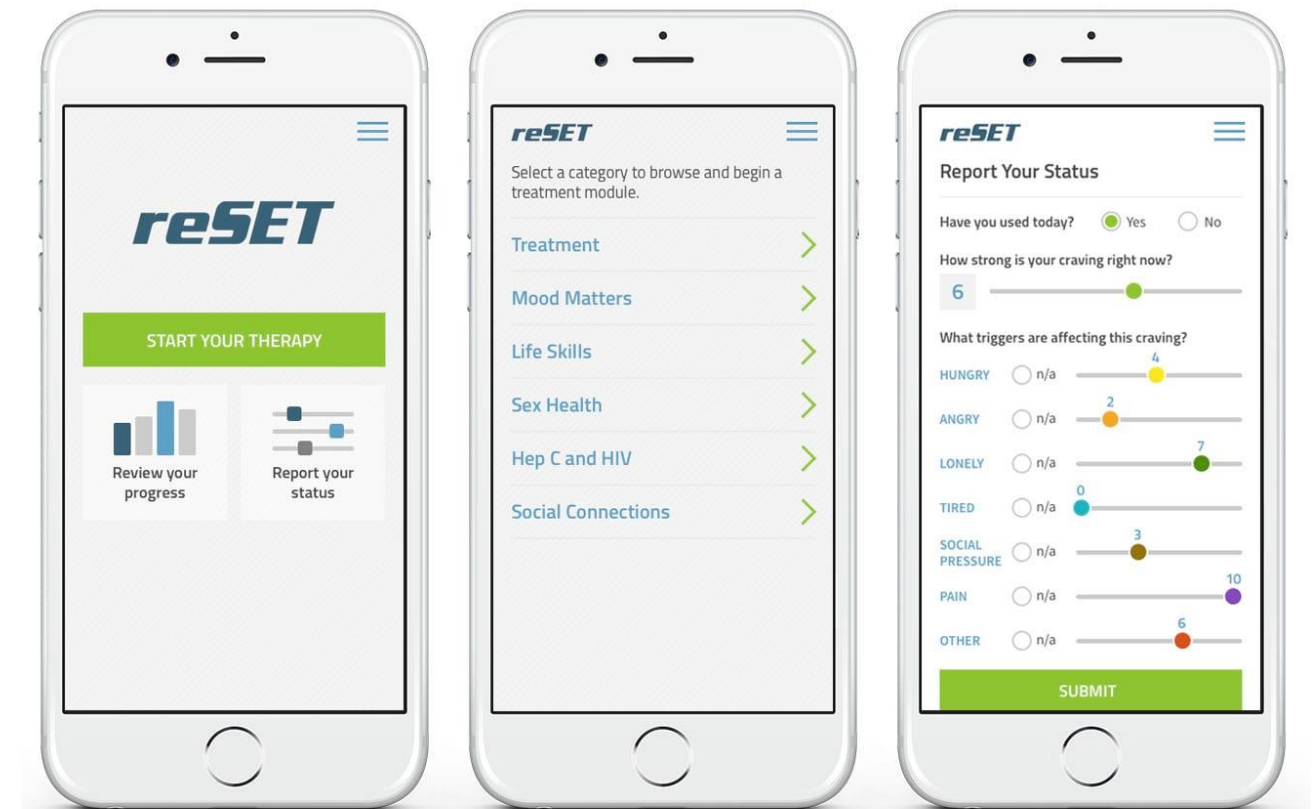
- FDA clearance May 2017
- Stroke Rehabilitation
- Early in-hospital acute care while plasticity high





Pear Therapeutics

- FDA clearance Sep 2017
- reSET® Subst. Abuse
- App used with CBT
- Increase abstinence, retention in program
- “Prescription Digital Therapeutic”





Akili Interactive Labs

- Game to treat ADHD
- Positive Late-stage trial
Dec 2017, 348 tested
- Seek De Novo clearance
late 2018/early 2019





Long path to clearance

- Started with Neuroracer
- UCSF/Ex-LucasArts collab
- Dr. Adam Gazzaley
- Began as aging adult research
- Multi-year study published in Nature
- That got VC interest in Akili, more years dev





The future - Good, Bad, Ugly, Sublime

- Each successful FDA clearance helps
- But they still will require big \$, years to dev
- Big Pharma - powerful but daunting partner
- Final results - good for finances, good for games industry, good for patients in need
- Next? Pain, Depression, PTSD, many more





Links for more info

- FDA device clearance:

<https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm>

- Akili Interactive Labs:

<https://www.akiliinteractive.com>

- Pear Therapeutics

<https://peartherapeutics.com/>

- MindMaze

<https://www.mindmaze.com/>





Thank You!

- Feel free to contact me:

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Happy to receive LinkedIn contacts too

