The case for collaboration and trial innovation in Alzheimer’s Disease
Imagine

What I’ll talk about

Our Mission

Why do we need trial innovations such as Adaptive Controlled Trials (ACT’s)?

Why do we need to work more collaboratively?
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Why do we need to work more collaboratively?
William (Bill) Utermohlen
Our Mission

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Why do we need to work more collaboratively?
Figure 1
Trends in Newly Approved Molecules and R&D Spending
United States, 1970-2009
The case of AD

Too little
Too late?

Diagnosis?

Fire and Forget trials

Intervention?
What do we need?

**LEARN** faster at optimal time/resource cost with **lower risk** for CONFIRMATORY PHASE

**CONFIRM** faster with **optimal** time/resource cost with **higher probability** for achieving PATIENT ACCESS

**Efficiency in trial conduct**
- Faster recruitment
- Robust standing infrastructure
- More data standardization & **data sharing**
**DISCOVER**

**Learning/exploratory activities**

**Phase I** improve exploratory properties:
- Better estimate of safety
- Better understanding of PK-PD

**Phase IIa & IIb** possibly combined - the sweet spot of current adaptive design:
- "Quick win/Quick kill"
- Test more doses
- Test more hypotheses

**LEARN**

**During the LEARN Phase, study design characteristics can be modified such as:**
- Population
- Endpoints
- Dosing regimen

**CONFIRM**

**Confirmation/Confirmatory Activities**

**Phase III** limited adaptation possible, but useful insurance:
- Start with more doses
- Sample size reassessment

**During the CONFIRM phase study design characteristics can be modified such as:**
- Drop doses
- Focus on sub-population
- Re-assess sample size
- Early Stopping
Existing Registries

Emerging Digital Platforms

Fit for purpose registry

Phenotyping Funnel

Trial Ready Cohort

Standing Adaptive POC trial

Governance & PMO

Trial platforms-solutions in a box

SITES

Confirm Trial

Confirm Trial

SC 1

SC 2

SC 3

SC 4

SC n

G2SS 1

G2SS 2

G2SS 3

G2SS n

Confirm Trial

Confirm Trial
Our Mission

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Why do we need to work more collaboratively?
IMAGINE

J&J ÷ Earth = 0.000002% of brain power
**Innovation Centers**
- 4 Innovation Centers on 3 Continents
- ~200 investments from 2013 - 2015
- Engagement across sectors

**JLABS**
- 6 sites in North America
- 120+ companies in residence
- 100% portfolio selected by ICs
- 50% portfolio in discussions
- 27 progressed to deals
- Engagement across all sectors

**JJDC**
(40+ years of VC investing)
- 142 direct investments and $884MM invested 2013 - 2015
- Partnership w/IC to form newcos on the rise
JnJ PPP’s: a Continuum of Collaboration
Conclusion

We **cannot afford not** to use everything at our disposal **to fight AD**

**Innovative ways to collaborate** provide opportunities to more effectively harness our global brain power and advance the field

**Adaptive trials and standing platforms** are essential tools to accelerate our learning