

There must be a better way...?

Creating a platform for collaborative research design



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The curious case of the CDRH advisory committee

Ummm.....Really...?

The Device	The Issue	Real ^ The Issue	The Company	The Patient Community	The FDA Team	The Evidence
Dexcom G5 Continuous Glucose Monitor (CGM)	CGM reading safe for dosing?	Medicare Reimbursement	Dexcom	Diabetes (Mostly Type 1, Mostly Insulin Users)	Clinical Chemistry and Clinical Toxicology Devices Panel	Modeling Data



Why
Modeling?

Based on data
from healthy 20-
year old
males?!!

Where's the
real world
data?

What about
older, sicker
patients?!

The data source that won the day...?

Patients!!!

- In -person testimony
- Letters to the advisory committee
- Videos from patients and parents



Building a better way...?

Creating a platform for collaborative research design



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Our Vision

Create paradigm-changing platform to **facilitate collaboration** among and incorporate the expertise of the broad health care community to **identify, understand and design solutions** to improve research about health and care

Inspirational Models



1

Consumer Goods
Innovative site providing platform for facilitating and rewarding invention of new consumer goods

Scientific Problem Solving
Ground-breaking site established to facilitate global cooperation around solving difficult scientific problems

2



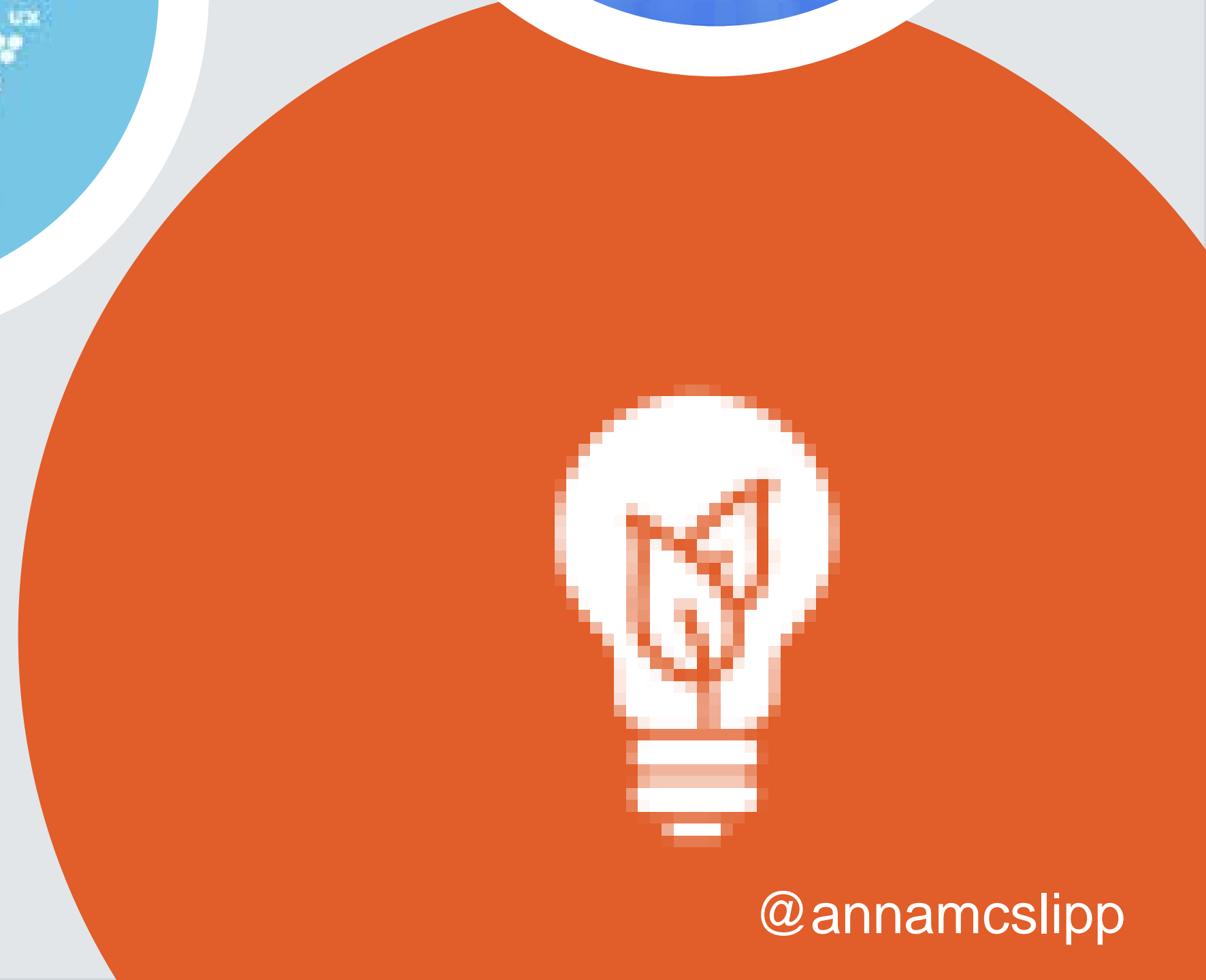
3

Experts Guiding Experts
Long-established platform for group problem solving, information sorting



4

Users Rating and Refining
Direct interaction between users and developers enables rapid refinement, iteration to improve app



VitalCrowd – Overview



VitalCrowd is a Web-based platform to facilitate collaboration among the broad health care community to identify, understand and design research methods and tools to improve health and care

Our Vision...

- Make research better!
- Make studies more relevant, efficient, accessible, practical
- Drive improvements in care that matter



How it Works – A Collaborative Platform for Research Design

DESIGNERS

Contribute unique expertise to research design

Patients/Caregivers

Refine protocols - give input on study design, protocol “workflow”, data collection, outcome measures
Propose trials based on their lived experience

Providers

Refine protocols to meet clinical, local researchers needs
Propose trials to meet clinical needs
Contribute insight to research aimed to transform clinical practice

Advocacy

Provide input into research design
Rally support/input from patients/caregiver/HCP members
Receive funding based on contributions, traffic to site

RESEARCHERS/SPONSORS

Gain early insight into potential problems, identify solutions, new/additional measures

Protocol Input

Are we measuring the right outcomes?
Is there a better way to collect data?
Are there any ethical/safety issues?

Patient Workflow

What are the burdens this trial would create? Are the benefits worth it?
How can we refine to make it work better?

Continued Access

Possible to go back to “crowd” with additional questions
Ongoing relationship with community



This Trial Would Work Better If...

Community Members ...

- ... View, refine and improve
- ... Advise on recruitment, dissemination
- ... are compensated – money and/or ‘points’
- ... are included as co-investigators (most ‘valuable’ contributors)

Researcher Collaborators ...

- ... review, refine, edit protocols
- ... conduct research, share findings

If Only There Were A Study That

...

Community Members ...

- ... propose studies, questions, needs
- ... rate, refine, promote other members' ideas
- ... are compensated – money and/or 'points'
- ... is acknowledged as co-author

Research Collaborators

- ... review, refine, seek funding

VitalCrowd Alpha



What we learned?

- Even “mobilized” and “engaged” patients and caregivers need guidance
- The “lift” needs to be easy(ish)
- Very few people are willing to dig into details
- What you think will work often doesn't

- Conceptual “MVP”
- Limited testing, mobilization
- Produced important insights

VitalCrowd Beta

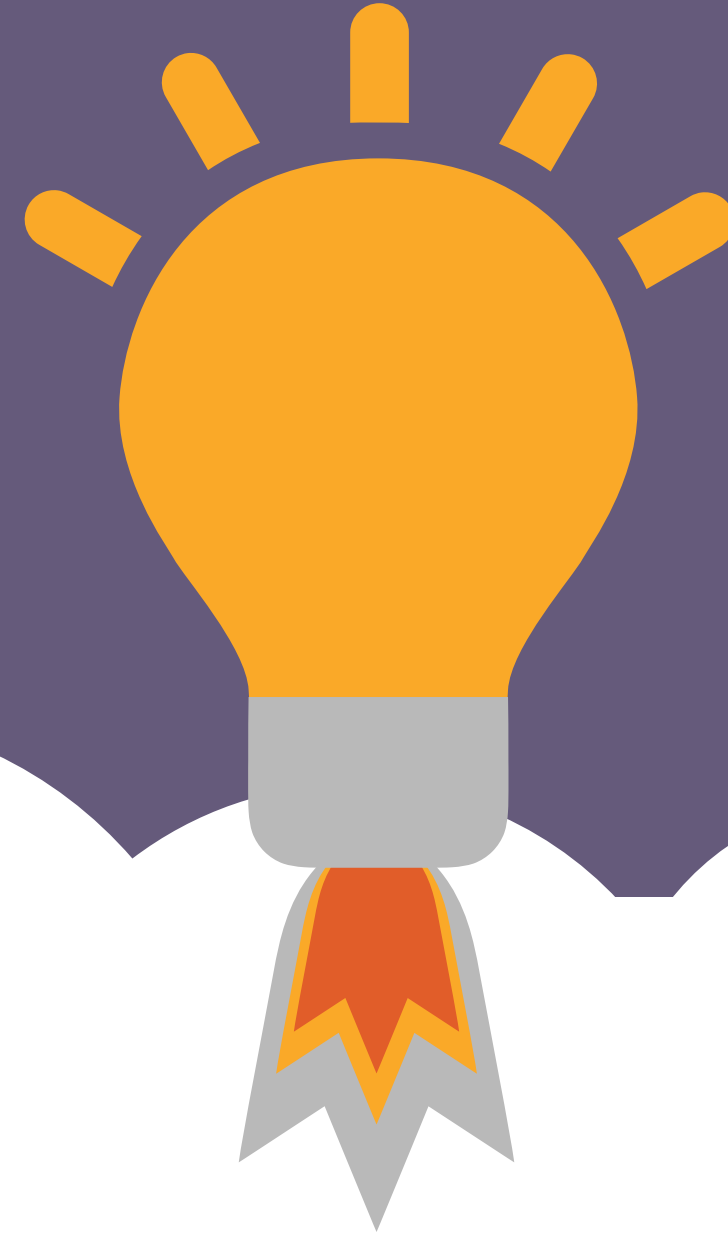


Design, develop and test VitalCrowd “beta” site

- Partnership with Janssen Research & Development Operations Innovation and develop beta-version of the Platform
- Test new platform on community co-design of two studies
- Create a roadmap for further development, testing and scaling of the platform



A Brighter Future for Research Design



Early Input

- Beginning with early discussions with agency and sponsor

Multi-faceted

- Not just symptoms, outcomes
- Not just outcomes, methods
- Not just methods, data types, sources, collection tools

Broad Based Input

- Larger group of patients, caregivers
- Representational of REAL patient population

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