There must be a better way…?

Creating a platform for collaborative research design
The curious case of the CDRH advisory committee
<table>
<thead>
<tr>
<th>The Device</th>
<th>The Issue</th>
<th>Real The Issue</th>
<th>The Company</th>
<th>The Patient Community</th>
<th>The FDA Team</th>
<th>The Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexcom G5 CGM</td>
<td>CGM reading safe for dosing?</td>
<td>Medicare Reimbursement</td>
<td>Dexcom</td>
<td>Diabetes (Mostly Type 1, Mostly Insulin Users)</td>
<td>Clinical Chemistry and Clinical Toxicology Devices Panel</td>
<td>Modeling Data</td>
</tr>
<tr>
<td>Continuous Glucose Monitor (CGM)</td>
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</tbody>
</table>
Based on data from healthy 20-year old males?!!

Where's the real world data?

Why Modeling?

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

@annamcsclipp
Building a better way…?

Creating a platform for collaborative research design

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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. **Quirky**
   - Innovative site providing platform for facilitating and rewarding invention of new consumer goods

2. **INNOCENTIVE**
   - Ground-breaking site established to facilitate global cooperation around solving difficult scientific problems

3. **StackExchange**
   - 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

@annamcslipp
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

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**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

@annamcslipp
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
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
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
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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