Project A)

"Empowering Real-Time Data on Drug Responses from Citizens"

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The development of new pharmaceuticals is an increasingly complex and expensive endeavor. On average, only 1 of every 5000 compounds discovered will ever reach commercialization. And each of these requires an average total investment of $1.3 billion[1]and 10-15 years of laboratory work, clinical trials and extensive regulatory reviews. Shortened product life cycles are placing further burdens on the economics of the process. New drug development, therefore, has necessarily evolved into a process predicated upon therapeutic innovation, while maintaining a clear commercial focus through the entire life cycle - the goal is to develop new drugs with clear competitive advantages and maximal commercial potential.

Numerous key decision points throughout the process assess project risks and ultimately determine the fate of product development, as well as the parameters for its continuation – the scale and scope of required clinical trials, choice of therapeutic indication, product profile and positioning, etc. As such, the pharmaceutical industry increasingly recognizes that successful new product development requires not only a well-documented understanding of the potential medical benefits and risks of a candidate drug, but also a clear, fundamental understanding of the market into which a drug is launched. Market research has therefore become a critical element of the drug development process and pharma has increasingly adopted an integrated process that closely aligns the activities of R&D and marketing teams. As a result, targeted information concerning potential patient needs, behaviors, predispositions and tolerances carries significant value and thus is the subject of significant expenditure within the pharmaceutical industry.

For a typical drug approaching phase II clinical studies, companies spend on average over $900,000 on market research to inform this single key decision point. Much of the compiled data, however, is qualitative and derived from limited population samples, and therefore only of limited value. At present, pharma typically relies primarily upon traditional methods of gathering such information – literature reviews, surveys, focus groups, and engagement of key opinion leaders. With the explosion of social media and the rise of the smart phone, this is changing.

The past several years has seen a fundamental shift in the communication of medical and health information by patients. The myriad of internet forums, twitter feeds, facebook and other social media platforms, where patients freely and openly share experiences related to their medical conditions and related treatments, represent a largely untapped storehouse of self-reported data with significant value to inform the drug development process.

The explosion of smartphone use presents another important opportunity to collect patient-reported health and medical data that would inform the drug development process. Mobile health management apps provide immediate value to the patient in terms of self-management of prescriptions, fitness and diet. In contrast to other forms of social media, such apps allow the collection of more structured patient-reported medical data. Importantly, data gathered by these apps

Project A)

is longitudinal, meaning data from individual users can be collected over extended time periods, providing an unusually rich portrait of patient behavior, motivation and response to treatment over time. At present, such data can only be obtained within the context of clinical trials, each costing tens of millions of dollars.
The pharmaceutical industry is not alone in its thirst for patient-reported health and medical data. The health provider and insurance industries ('payors') have a vested interest in similar such data, particularly surrounding prescription usage and comparative effectiveness of various therapeutic options, as a means of lowering costs in an increasingly competitive market.

Over to You

A- Empowering Real-Time Data on Drug Responses from Citizens

G	Organization	Last name	First
A	GE Healthcare	Chapman	Rowan
A-Anchor	Sage Bionetworks	Ferte	Charles
A	Sagebase BOD	Ford-Hutchinson	Tony
A	Boehringer Ingelheim	Fowler	Claire
A	Traitwise	Fryklund	Rechelle
A	Color Genomics	Gil	Elad
A	Cloudera	Hammerbacher	Jeff
A	Forbes	Herper	Matthew
A-Anchor	Sage Bionetworks	Hoff	Bruce
A	Merck	Johnson	Jason
A	OneMind4Research	Johnson	Stephen
A	OneMind4Research	Larson	Stephen
A	miRcore	Lee	Inhan
A	QCRI	Meier	Patrick
A	Code for America	Pahlka	Jennifer
A	Life Technologies	Sachs	Alan
A-Lead	MyOwnMed	Seyfert-Margolis	Vicki
A	Xconomy	Timmerman	Luke
A	Google	Treuille	Adrien
A	Lulu	Young	Bob

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Project Overview- Major Themes

- Home Chief Medical Officer managing child/children with ADHD
- Provide web/mobile platform to match parents with these children using the match.com platform, or Facebook or combo
- Privacy is a key issues because of stigma
- Pilot for school systems to provide strategies for accommodation
  - Data collection including drugs used, how and when
  - Mobile monitoring of children's habits- sleep and eat and exercise
  - Tools to build community of Home Chief Medical Officers
  - Incentive for early adopters – is the ability to monitor and view the data itself
  - Value of data goes up with number adopters
  - Secure anonymous place to chat with other Home Chief Medical Officers
- Start with pilot programs of parents in several school systems as partner not owner
- Provide feedback, recommendations to school

Potential alignment with existing Commons' approaches

- Data collection is important in that engages with Common's approaches
- Quality of data not as important as sophistication of mining it
- Data grows in value with the collective and expanding user base
- Platform could be SAGE platform or other for or non-profit entity
- Can provide an initiative for other similar issues
- For profit- data GPO, creative common license
- Do we open up all anonymized data- do you need to share openly

Unmet needs and issues

- How do we trust the quality of the data uploaded remains challenging
- There is no tracking system
- Big issue around public/private nature of the data and identification
- Ultimately tie to healthcare provider critical

1-year vision for the future of this project

- Develop the web/mobile application with a tracking system
- Implement in a 3 school systems
- Report the experience