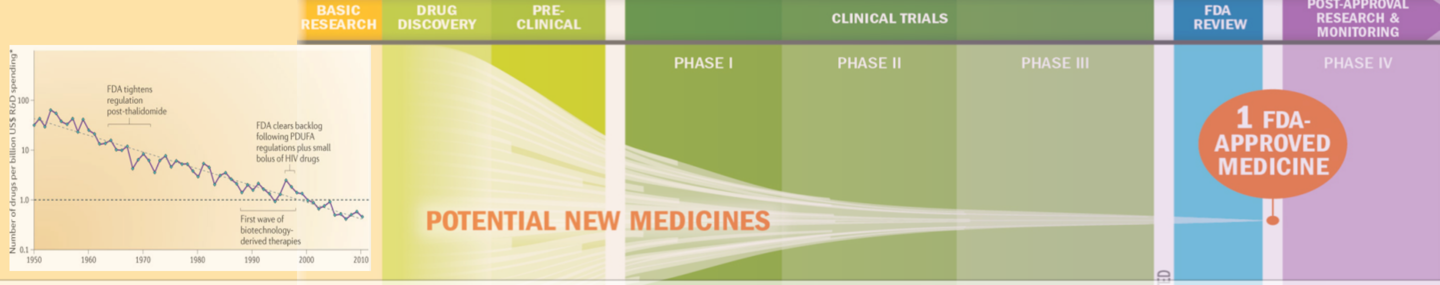

Are we reaching the *wrong conclusions* during the drug development clinical trials process and missing blockbuster opportunities?

It has become progressively more expensive to develop a drug. *Eroom's Law*, a wry reference to Moore's Law, Eroom is Moore spelled backwards, states that "the cost of developing a new drug doubles approximately every nine years despite improvements in technology".

Part of the problem is that the clinical trials process itself is part testing, part learning. When a drug, diagnostic or device meets humans for the first time in a clinical trial the outcome, by its very nature is somewhat unpredictable. Ergo it is often quite difficult to get a complete picture of what is actually going on before the trials design process must begin for the next phase of the study. Furthermore the clinical trials process relies on a complex web of human motives and 'agency' commonly rooted around keeping a program going and the funding flowing. In order to manage the process the trial is designed around achievable end-goals, hiring effective statisticians and is usually anchored with the experience of self-appointed medical experts. While this may sound logical, the process has already narrowed the bounds of an acceptable outcome, guaranteed that the statisticians are bound to try to prove a certain outcome and sent us down an inexorable path on a decision-tree that the experts will not likely reverse since they have staked their reputations on their counsel.

Perhaps these clinical development scenarios seem familiar. They are common scenarios.

The current approach and status quo leads to optimization of the clinical trials process in a manner that introduces significant human bias at many points in the process. Granted, we have optimized the process and reached a comfortable point that seems to work to some degree for industry, the regulators and the marketplace, but the current drug development process is almost unsustainably expensive, time consuming and inefficient.

To borrow a phrase from Machine Learning we have reached a 'minima', but it is possible this is a 'local minima'. In plainer English: we have found a solution and optimized our drug development processes around this solution...but we are not 100% sure this is the best solution. The statistics and economics suggest we could do a lot better.

The hazards of hidden assumptions

As machine learning developed over the last few decades it became clear that one of the pitfalls in the process of developing effective algorithms *was the skewed logic of the humans themselves*. The assumptions underlying the structure of the classifying algorithms developed from human presuppositions were often flawed. In other words, the chain of logic between humans and pure math was corrupted. It took decades to develop the tools and gather enough data to overcome this roadblock. These advancements became the underpinnings of the Search, Image recognition, voice recognition, advertisement and smart systems we use everyday on our mobile phone.

It is easy to see that medicine has a long history of bias. One only needs to question why the terms "Standard of Care" and "Evidence-based medicine" even exist in common medical parlance. They are evidence of the intrinsic bias and self-affirmation that exists within the community largely responsible for the clinical phase of the drug development process.

The question is - is there a way to uncouple wasteful human fallibility from valuable human intuition and improve the process of clinical drug development, what has to be one of the most important process optimization challenges of the 21st Century?

Uncorrupted data?

Getting near real-time, unfiltered data directly from the patient is a new frontier of digital medicine. Just like the data flowing from your web-browser or mobile device, the innovation lies in the data handling, processing and analytics to provide the humans with actionable insights. In addition, building a feedback loop between patients and organizations performing clinical development can provide significant leverage and benefit to both the patient and the Health Care Provider. This is the same conceptual underpinning that has catapulted companies like Google, Facebook and Amazon to dominate their respective markets in the consumer space - they all rely on a personalized and direct feedback loop between their data centers and their customer, the difference here is that the technology is being used to massively improve the data gathering around clinical trials rather than sell the user a new refrigerator.

There are obviously differences in the regulation of medical data versus a consumers buying habits and while patients may vest their trust in health care providers, they may feel more ambivalent about Pharma companies. However the potential long term upsides of reduced drug prices and increased therapeutic options may be attractive. Parallels exist within 'fin-tech' financial services companies where information on individual transactions is less readily available, but mathematically 'abstracted' versions of data such as credit reports, annual transaction volumes etc. flow more freely. This goal is to let the data and the feedback loops drive the analysis pipeline and optimization process minimizing the human influence, agency and confirmation –bias that afflicts current data processing methodology in drug development despite all of the best intentions otherwise.

What sorts of clinical indications could benefit from this approach?

Anything subject to time-dependent subjectivity:
We know that if we ask someone what they had for dinner every day for a month at the end of that month that the data will be intrinsically inaccurate. We also know that if the specific details of the meal are recorded at the time of consumption that the data 'diary' is probably pretty accurate.

Any phenomenon that is relative or context dependent:
Unless the sensation is extreme, memories of feeling cold, uncomfortable, too hot or out of breath are typically transitory if the social or physical environment is changing, especially if discomfort, for example, was changing on an hour by hour basis. While it seems like this data may be hard to analyze it is the nature of the data itself, its cadence, amplitude and second order heuristics that may be important - more than a deep understanding of why.

Any emotional or mental status:
Neurological phenomena are generally subjective and also subject to feedback loops within the patient and often change in response to human interaction. For instance, if a patient is feeling lonely and miserable they are unlikely to be able to change their state dramatically based on their own self impetus. It requires input. Other examples are physical pain and emotions such as fear, anger, sadness, depression, joy, disgust, surprise, trust, acceptance or anticipation. All of the memories of these states are often quick to change so again, capturing the subtle nuances within the data itself can be helpful.

About the author: