Inspired by Agile – Getting Stuff Done in Pharma

Today, it is not enough to develop an exceptional drug. Pharma companies must also offer exceptional support products and services alongside their brand. These are not (and should not be) static offerings. Rather, they must be flexible, efficient and have longevity to accommodate the increasingly dynamic world of pharma – especially in therapy areas inundated with new treatments, updated indications and new avenues for patients to take part in their own care.

With increasing dependence upon technological innovation in pharma, there is value in looking at how the tech sector thinks through problems. In fact, many pharma companies are already starting to do this. As reported in the Financial Times in November 2018, Novartis – currently developing products with the help of artificial intelligence (AI) – sees itself as "shifting from the mindset of traditional pharma company to [one] more inherently agile, typical of a tech company."

No wonder the FDA recently drafted a regulatory framework to review digital health device applications. "An agile regulatory paradigm is necessary to accommodate the faster rate of development and potential for innovation in software-based products," the FDA wrote in its program working model. "It is important for public health to address these distinctive aspects of digital health technology."

But what really is Agile?

Developed in 2001 by software engineers, Agile is rooted in four principles:

- 1. Individuals and Interactions over processes
- 2. Working software over comprehensive documentation
- 3. Customer collaboration over contract negotiation
- 4. Responding to change over following a plan

These ideas present a positive challenge, rather than a prescriptive solution. Being Agile necessitates being flexible, faster and efficient, while maintaining or improving quality. This can be something as simple as solving a problem with an iterative approach vs. a rigid, pre-planned approach followed from start to finish.

Bringing the concept of Agile to pharma research and strategic consulting

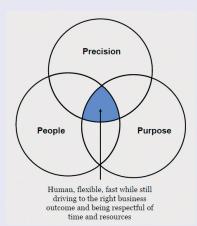
Pharma is not at all like software – we cannot just launch a product into the market, get feedback and produce a new version the week after. It's not possible to 'cut and paste' Agile into our world. However, we can take inspiration from Agile to achieve better outcomes more quickly.

Three elements are essential when applying Agile thinking to consulting challenges:

- Precision: being able to effectively deploy critical thinking
- People: having the right people involved at the right time
- **Purpose:** making sure the purpose is outcomes-focussed

Striking a balance among these three elements means getting the benefits and avoiding the pitfalls in projects.

In the pharma sector, it is easy to rest on our laurels and not expand beyond tried-and-tested approaches especially with the complexities of pharmacovigilance presenting a barrier. Large programs of research are often planned out months in advance, with tight timings and pre-defined outcomes.



As research consultants, we are often called upon to give input into certain aspects of research planning. By bringing Agile thinking to fore in these conversations, we can help clients make decisions that will be inherently less risky with better outcomes. This could be something as simple as taking a brief pause at the beginning

of a project to thoroughly consider the Core Question the project is addressing and using it as a north star for designing materials and outputs. This means our clients can act quickly and effectively.

Agile thinking can be applied to many therapy areas. Take rheumatoid arthritis, for example. As new biologics, novel delivery mechanisms and biosimilars are launched, pharma companies are expected to stay relevant and produce top-of-the-line products and services to accompany these treatments. Importantly services need to stand out and ensure a ROI and therefore it's important to consider the following questions to ensure viability:

- Precision: How can we think differently to stand out in a saturated market? What are our challenges and limitations? What is a must have vs. added value?
- People: How do you communicate the benefits of the products and services to the relevant customers? In RA (like many therapy areas) it's not just about improving the patient experience it's about ensuring HCPs buy-in to the concept
- Purpose: What is the outcome/behaviour we want to achieve? (ie adherence, increased uptake, QOL outcomes)

Takeaways tips

To conclude, we leave you with some tips you can apply to projects to make them more Agile:

- Have small, stable, relevant teams everyone with a purpose
- Identify your key emotionally-invested stakeholder involve them up front and keep them involved
- Define the Core Question and break it down into clear 'researchable' components to maximise efficiency of time, effort and spend
- Facilitate simple planning sessions with tightly defined agendas: right people, right process, right precision
- Build in Review sessions after each phase iterate learnings
- Keep it flexible. When things change, document the change and the impact – revise the Core Question, how it breaks down and the priorities/outputs

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