



PhUSE US Connect 2021

Paper LE06

One Sprint at a Time – Agile Transformation in Clinical Research

Steve Benjamin, Syneos Health, North Carolina, USA

Aman Bahl, Syneos Health, Ontario, Canada

June 17th 2021

— Author's Bio

Steve Benjamin is a Director, Biometrics FSP 360 with Syneos Health supporting biostatistics, statistical programming and global contract teams with our sponsors. He has been with Syneos Health for 12 years, enjoying high performers and teams and their contributions to delivery, new solutions and approaches.

Aman Bahl is an Associate Director, Statistical Programming with Syneos Health, and has 20 years of Technology and Data services experience including 18 years of Clinical industry experience in the areas of project management, team management, statistical programming and other statistical services. Aman enjoys outdoor sports, trekking, travelling and volunteering.

Adaptability is the behavior and Agility is the consequence



Picture Source: <https://www.pinterest.ca/pin/621004236094076532/>
[https://en.wikipedia.org/wiki/Surfing#/media/File:Mavericks Surf Contest 2010b.jpg](https://en.wikipedia.org/wiki/Surfing#/media/File:Mavericks_Surf_Contest_2010b.jpg)

Agile Examples

Agile at Spotify



Picture source: <https://www.freepnglogos.com/images/spotify-logo-png-7053.html>

Airlines redraw routes to match shifting passenger demand

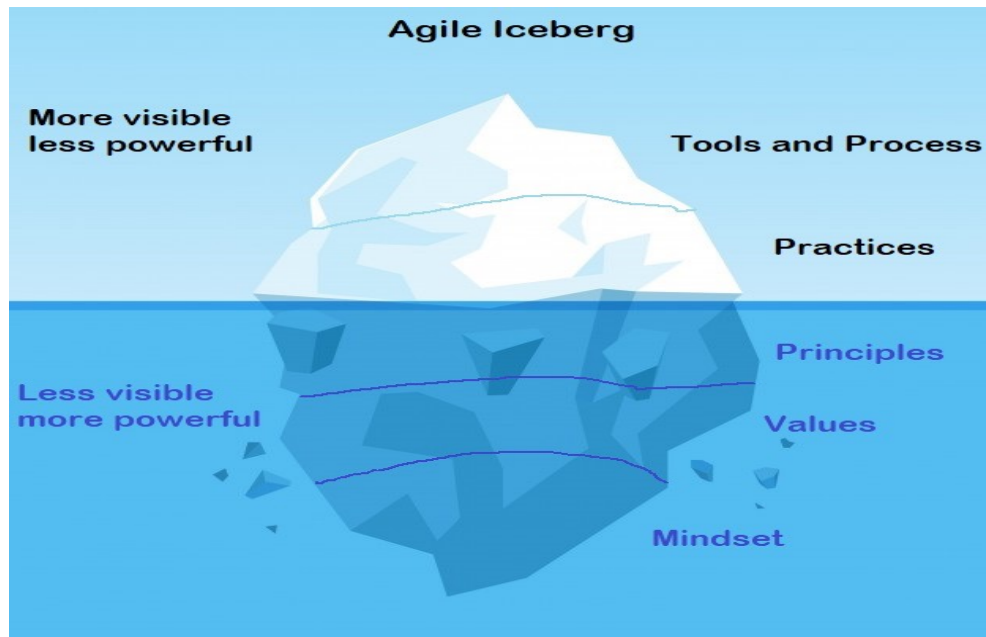


Picture source: https://www.freepik.com/premium-photo/airplane-taking-off-from-airport_5057943.htm#page=1&query=airplane%20sky&position=13

Agile Iceberg - Doing Agile and Being Agile

As quoted by Edward T. Hall, an American anthropologist that “Culture is not made up but something that evolves which is human”¹

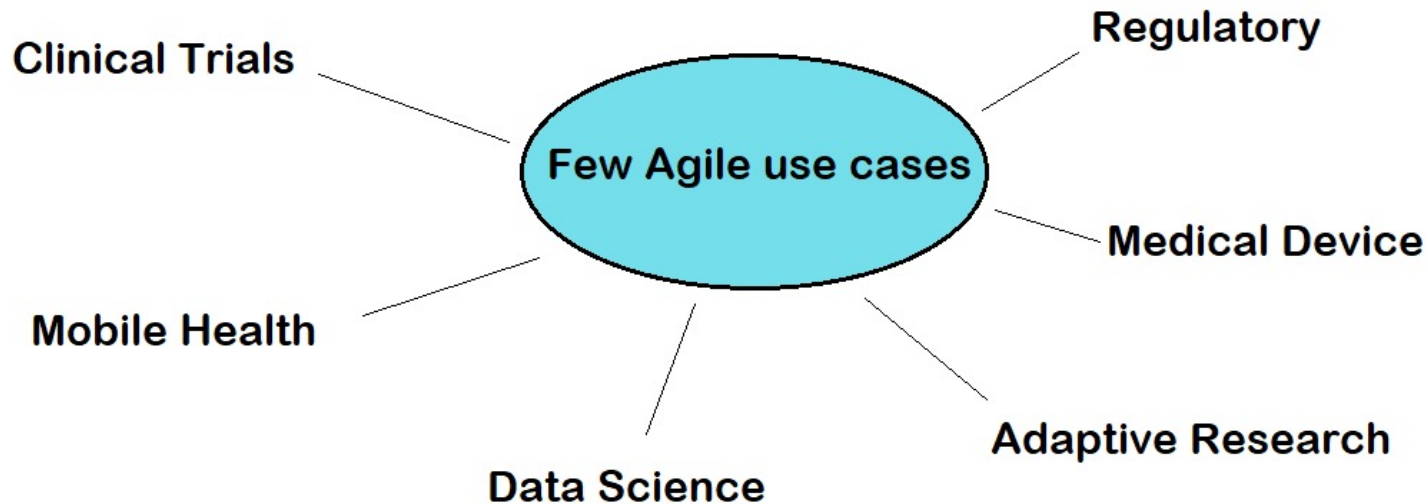
¹ https://www.brainyquote.com/quotes/edward_t_hall_201512



Need for Agile in Healthcare

- Improve the way clinical trials are planned and designed
- Better quality clinical protocol designs and reduced amendments
- Dealing with uncertainties Ex: Pandemics
- Faster drug development and regulatory approvals for emergency use authorization. Ex: covid vaccines
- Leverage modern digital sciences and technologies to accelerate development of new therapies

Some Agile use cases

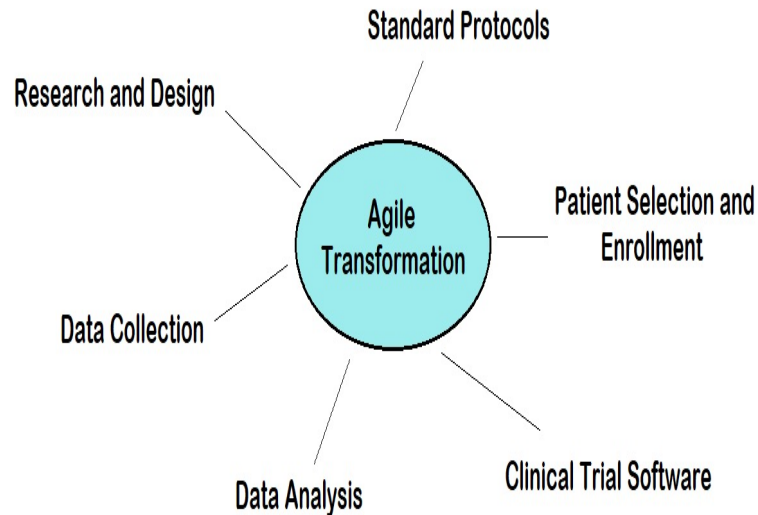


Applying the Agile Mechanism in the Clinical Trials

“The key is building a flexible and agile trial platform. If you can see, early on, that a protocol isn’t working, the scalable platform design allows you to swap in another, almost the way you would replace a light bulb”² - Nick Kenny, CSO, Syneos Health

Few examples of agile use in clinical trials:

- Beat AML master clinical trial²
- Elligo Health research site-less trial pilot²
- CDISC 360 project from Clinical Data Interchange Standards Consortium (CDISC)³
- ACORN AI intelligent trials solution⁴
- Electronic patient-reported outcomes (ePRO) by Clinical Ink⁵



² <https://www.syneoshealth.com/sites/default/files/thought-leadership-articles/pdf/Biopharma-Embraces-Life-Fast-Lane.pdf>

³ <https://www.cdisc.org/cdisc-360>

⁴ <https://www.medidata.com/wp-content/uploads/2020/10/Acorn-AI-Intelligent-Trials-FAQ.pdf>

⁵ <https://www.clinicalleader.com/doc/epro-and-agile-methodology-a-winning-end-to-end-solution-for-oncology-studies-0001>

Agile and Regulatory Compliance

- Clinical agile methodology can easily adapt to the challenges presented by the changing regulations, guidelines, and emerging technologies
- The 21st Century Cures Act provides expedited approval pathways for revolutionary medicines⁶
- TIR45 guidance document from AAMI to steer medical device design and development companies on how to work agile within a regulated process⁷
- US FDA explicitly recognized agile as an acceptable standard in January of 2013, referring to AAMI TIR45 guidance document and added it to its list of the approved standards to be used by the manufacturers⁸

⁶ <https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act>

⁷ https://my.aami.org/aamiresources/previewfiles/TIR45_1208_PREVIEW.PDF

⁸ https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard_identification_no=30575

Agile in Medical Device Development

- Medical device companies can incorporate agile methodology to improve the quality of the medical device software and continuously improve their functionality
- Agile focuses on aligning the final product more precisely with the user's needs
- MDevSPICE®, an integrated framework of medical device software development best practices using Agile methodology, has been developed to assist software medical device developers to reach regulatory compliance⁹

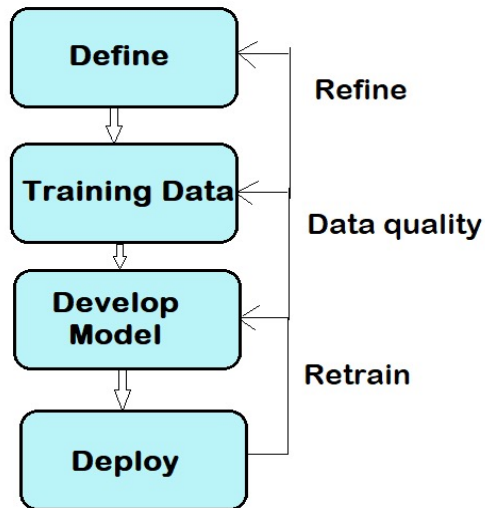
⁹ <https://publications.waset.org/10006565/supporting-embedded-medical-software-development-with-mdevspice-and-agile-practices>

Using Agile Methodology in Data Science

“If practicing Agile Software Development produces value from learning through failing fast and safe... then a Data Scientist's role in an Agile team is to help the team to fail faster!”¹⁰ - Christos Hadjinikolis, Data Scientist at Mcubed London 2018

Some examples of agile use in data science are as follows:

- The Team Data Science Process (TDSP) is an agile, iterative data science methodology to deliver predictive analytics solutions and intelligent applications efficiently¹¹
- DataOps is an agile methodology for developing and deploying data-intensive applications, including data science and machine learning¹²



¹⁰ <https://2018.mcubed.london/sessions/data-science-agile-way/>

¹¹ <https://docs.microsoft.com/en-us/azure/machine-learning/team-data-science-process/overview>

¹² <https://www.oracle.com/a/ocom/docs/oracle-ds-data-ops-map-r.pdf>

The Agile Approach to Adaptive Research

The use of adaptive design has been shown to shorten product development time and is therefore very cost-effective for clinical organizations.

Other advantages of Agile approach are bringing new drugs and vaccines to patients faster, cost reduction, improvement in patient selection, and making the whole clinical trial process more flexible, adaptable, and being able to respond to change.

One of the example of agile use in adaptive research is :

The Global Coalition for Adaptive Research (GCAR) is a non-profit established in 2017 to speed the discovery and development of cures for patients with deadly diseases.

GBM AGILE (Glioblastoma Adaptive Global Innovative Learning Environment), sponsored and managed by CGAR, represents a novel clinical trial system for evaluating and potentially approving multiple treatments for glioblastoma. It is the world's first global adaptive clinical trial for brain cancer¹³

¹³ <https://www.gcaresearch.org/>

Agile in Digital Health Solutions

Some examples of agile use in digital health solutions:

- Iora Health built its electronic health records to respond to its agile and team-based approach to coordinate care¹⁴
- mHealthDroid is an open-source android implementation of a mHealth Framework designed to facilitate the rapid and easy development of biomedical apps¹⁵
- The NeoTree is a fully integrated digital health intervention that combines immediate data capture, entered by healthcare workers (HCW) on admission, while simultaneously providing them with evidence-based clinical decision support and newborn care education¹⁶
- MindClimb - A mobile phone-based application for use during cognitive behavioral therapy for adolescents with anxiety¹⁷

¹⁴ <https://pubmed.ncbi.nlm.nih.gov/26250083/>

¹⁵ <https://pubmed.ncbi.nlm.nih.gov/26329639/>

¹⁶ <https://gh.bmj.com/content/bmjgh/4/1/e000860.full.pdf>

¹⁷ <https://mhealth.jmir.org/2020/12/e18439>

Challenges of Adopting Agile

Agile development methods are designed to produce smaller quicker deliverables but are typically less formal in the documentation produced that can be a challenge when working in a regulated environment.

Every new methodology brings uncertainty, but without uncertainty, there is no innovation. Clinical organizations need to change their mindset and culture to embrace change and uncertainty.

For the clinical industry to excel, an agile and efficient integrated platform needs to be developed. Even though the new technology won't be adopted overnight and the shift to virtual trials won't be entirely straightforward, clinical research organizations must be agile to keep up with the ever-changing demands in this new era.

Conclusion

Per Pearl Zhu (Author, Digitizing Boardroom: The Multifaceted Aspects of Digital Ready Boards), Agile is more a "Direction," than an "End," a philosophy and mindset at board level¹⁸

Coming from software development agile transformation is not just about technology. It is about a new way of thinking. It is more collaborative, more creative, and much more effective than other methodology.

Agile innovations can target patients, health care practitioners, and healthcare providers and can help in transforming services, customer experiences, and internal practices within the organization.

Agile transformation will help in enhancing the patient experience and will also help in optimizing overall clinical trial and key areas such as patient enrollment, monitoring, and site management. It will also enhance creativity and help in finding better and innovative solutions and redesign patient care.

¹⁸ <https://www.goodreads.com/quotes/7883455-agile-is-more-a-direction-than-an-end-a-philosophy>

Author's Contact Information

Your comments and questions are valued and encouraged. Contact the authors at:

Steve Benjamin

Director, Biometrics FSP 360

Phone: +1-919 923 6639

E-mail: Steve.Benjamin@syneoshealth.com

Web: <http://www.syneoshealth.com>

Aman Bahl

Associate Director, Statistical Programming, Clinical Division, Syneos Health

Phone: +1 905 399 6715

E-mail: Aman.Bahl@syneoshealth.com

Web: <http://www.syneoshealth.com>

Shortening the Distance from Lab to Life[®].

