PhUSE EU Connect 2018

Paper PP17

The 5R's of Innovative Digital Technologies

Anna Hedman[1], Tracey Lavery[2], Charlotte Lomberg[1]
[1]Early Clinical Biometrics, Early Clinical Development, IMED Biotech Unit, AstraZeneca, Gothenburg, Sweden
[2]Early Clinical Biometrics, Early Clinical Development, IMED Biotech Unit, AstraZeneca, Cambridge, UK

ABSTRACT

Several Innovative Digital Technologies have already been implemented into Early Clinical Development studies at AstraZeneca. These technologies offer the potential to capture more specific, targeted and better quality data to help support decision making, but with new data collection methods comes new challenges. This poster focuses on how the Data Managers from Early Clinical Development Biometrics at AstraZeneca have demonstrated the 5 R's of Innovative Digital Technologies when assisting the teams; bridging knowledge in collaborating with digital technology vendors, bringing quality to the data collected, defining clear end to end data flows, and focusing on quality control and data security.

INTRODUCTION

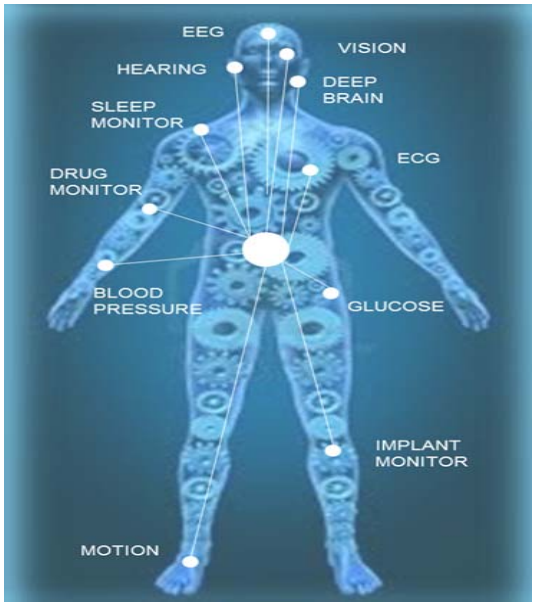
The following paper will dive a little bit further into how Data Management in Early Clinical Development at AstraZeneca have developed the 5R's of Innovative Digital Technologies to support successful implementation of future digital technologies in clinical trials.

DIGITAL TECHNOLOGIES IN CLINICAL TRIALS AND THE 5R'S

Early Clinical Development at AstraZeneca have been gaining experience of using innovative digital technologies in our clinical trials, for example an Activity App for 6-Minute Walk Test and Maximum Continuously Walked Steps (figure 1). Innovative digital technology will transform data collection. A vision is that all data will be collected passively (figure 2).

Figure 1. Activity App.

Figure 2. Vision: All data will be collected passively.



Having digital technologies in clinical trials is great – but you need someone to support these new data collection methods. Data Management in Early Clinical Development have therefore developed the 5R's to help incorporate the Innovative Digital Technology easily (figure 3).

- We bring forward the Right Technology – Timing and early involvement of Data Management is crucial to build a robust foundation from the start. Keeping quality of life for patients by less frequent site visits.
- We deliver the Right Quality – Improving data collection, performing quality control and observe data security for example.
- We use the Right Process – Getting the right level of data and optimizing the data flow. By getting the process right we hope to get the setup time from the current 5-6 months down to under 2 months.
- We engage the Right Collaboration – Being early involved in collaborations to build a solid framework for the data.
- We practice the Right Learning – Assisting with expert advice and bridge knowledge between different functions, for example study teams, biometrics and external vendors.

Applying the Data Management 5 R's of Innovative Digital Technologies in Early Clinical Development at AstraZeneca, we are gaining valuable experience for future routine use in our trials.

Figure 3. 5R's of Innovative Digital Technologies

CONCLUSION

- Early Clinical Development at AstraZeneca are gaining experience by using Innovative Digital Technologies in studies. The vision is to make real time data entry streaming devices common in our trials, ensuring standards, device set ups and real time data access, enabling real time decisions.
- Data Management in Early Clinical Development at AstraZeneca have developed the 5R's to help incorporate the Innovative Digital Technology easily.
- Data Management in Early Clinical Development at AstraZeneca are innovating the data process, to deliver a solid framework with high data quality for early decision making. Getting it right first time will save time and cost to reach patients faster.

Data Management are innovating the data process. Getting it right first time will save time and cost, but also ensure high data quality for decision making in order to reach patients faster. Data Management are here to support successful implementation of future digital technologies.

ACKNOWLEDGMENTS

Extended thanks to AstraZeneca functions within Cardiovascular, Renal & Metabolism Translational Medicines Unit and Study Operations, Intelligent Pharmaceuticals, Scientific Partnering & Alliances and Precision Medicine & Genomics for the fantastic collaborations to successfully implement Innovative Digital Technologies into Early Clinical Development studies at AstraZeneca and driving future initiatives.

CONTACT INFORMATION

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

Author Name	Anna Hedman
Company	AstraZeneca
Site	Gothenburg
Email	Anna.hedman@astrazeneca.com