

The 5R's of Innovative Digital Technologies

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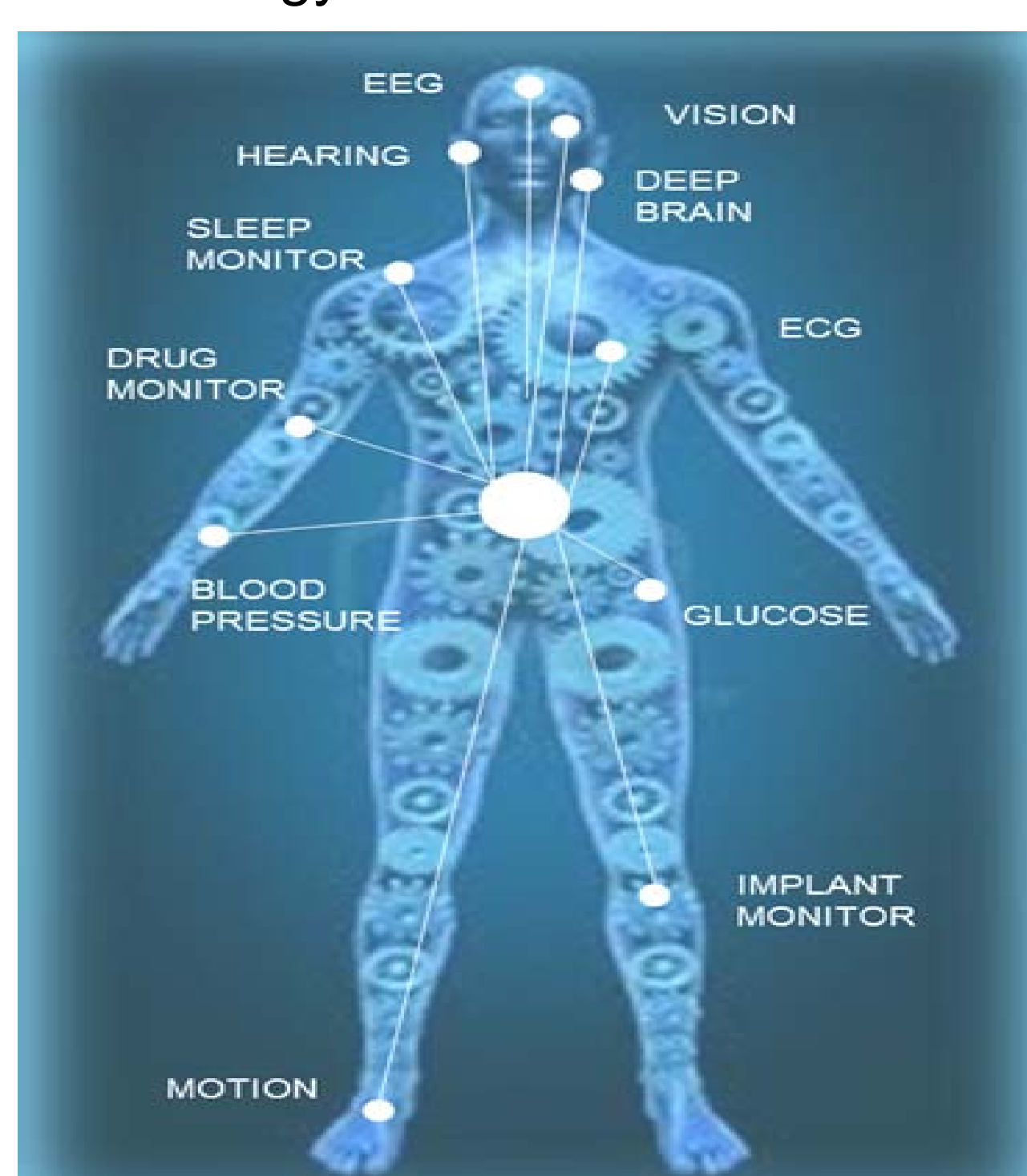


Introduction

Several Innovative Digital Technologies have already been implemented into Early Clinical Development studies at AstraZeneca, for example an Activity App. 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.

Vision: All data will be collected passively

Innovative digital technology will transform data collection.



Activity App

6-Minute Walk Test and Maximum Continuously Walked Steps. (Cardiovascular studies)



5R's of Innovative Digital Technologies



Right Technology

Timing and early involvement of Data Management is crucial to create a robust foundation, using the right digital technologies to enable timely, high quality data for early decision making, *returning to growth*.



Right Quality

Improving data collection, quality control and data security, with forward thinking, moving into future technologies and *achieve scientific leadership*.



Right Process

Defining clear standards and end to end data flows is a key enabler in getting the right level of data and optimizing the data flow from study design, collection and cleaning to analysis and submission.



Right Collaboration

Early involvement of Data Management in collaborations with e.g. internal departments and functions as well as external digital technology vendors, building a solid framework.



Right Learning

Assisting the wide collaborations with expert advice and bridging knowledge between e.g. external vendors, study teams and biometrics, *being entrepreneurial*. Ensure to get it right first time.



Achievements

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.

Right Quality and Right Process. Optimizing the device to deliver quality data, giving input to improvements. Improving data collection, quality control and data security along with defining a clear end to end data flow.

Right Technology and Right Collaboration. Meeting regulatory requirements and keeping quality of life for patients by less frequent site visits. Creating a robust foundation for delivery of the right data for decision making.

Right Learning. Gaining knowledge on how to best incorporate Innovative Digital Technologies in Early Clinical Development trials. Assisting with expert advice and bridging knowledge between study teams, biometrics and external vendors.



Conclusion and Next Steps

- 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.

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