CLINICAL INVESTIGATION

Interview with Graham Clarke

Dr Graham Clarke is the senior director and head of the respiratory and inflammation unit, Early Clinical Development, at Quintiles, London. He leads the development and execution of inhaler generics and inhaler characterization studies, biomarker identification efforts and the development of challenge models of inflammation across several therapeutic areas. After previous appointments in molecular and forensic analytical biology and subsequently training as a clinical physiologist at the Royal Brompton Hospital, London, UK, Dr Clarke has served in a variety of respiratory clinical research environments. He is an honorary research fellow in cardiothoracic pharmacology at Imperial College London's National Heart and Lung Institute. Dr Clarke completed a PhD in respiratory pharmacology and physiology with a focus on airway and vascular hyper-responsiveness in asthma at King's College, London, UK.

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Q Tell us a little about your personal journey in the field of clinical trial research

I started off as a molecular biologist in oncology research at Cancer Research UK (formerly Imperial Cancer Research Fund) followed by working on scene-of-crime forensic samples as a DNA analyst for the Laboratory of the Government Chemist. These experiences gave me insight into developing quality control procedures and developing insights into mechanism of disease and tissue function. These initial experiences inspired me to develop my journey further into clinical research.

Following these initial laboratory-based experiences, I developed my respiratory clinical research interest during my time training as a clinical physiologist at the Royal Brompton Hospital, London. I then pursued a PhD in airway pharmacology at King's College London evaluating the relationship between vascular and airway hyper-responsiveness in asthma. Following a postdoctoral position at Imperial and working for a small niche CRO, I joined Quintiles. I now head respiratory and inflammation research in early clinical development for Quintiles based in London.

Q How would you describe your role at Quintiles?

I lead a multidisciplinary group of biomarker scientists and clinical respiratory specialists – as well as coordinating an integrated group of clinicians and project managers. I lead the scientific and operational programs for first in patient respiratory-indicated compounds.

Q In a recent presentation, you discussed the use of adaptive tools to enhance early clinical development – could you briefly summarize the take-home points of your talk?

There is a real need to improve the drug development process so that new and better medicines can get to patients sooner. Changes in the way we approach clinical trials have enabled patients to enroll sooner into the drug development process. This is important, both to address very quickly the drug safety and tolerability question, but also to give us insights into the efficacy of a

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compound in a particular disease subtype. In my talk I focused on how adaptive designs have improved the delivery of these studies to the market, but also highlighted the inclusion of biomarkers and the role of precision medicine in developing new strategies going forward for drug development.

Q What do you think will be the greatest change in the next 5–10 years in the field of early clinical development?

The use of network biology is important, and how we use data to identify responders and nonresponders is critical to how we develop a more tailored approach to drug development. The use of genomics, and the use of transcript or proteomics to identify key biomarkers that separate one particular patient phenotype from the next allows more targeted therapies; this is going to be important. The biggest challenges we see are not necessarily in how these technologies are to be incorporated, but how these derived data can be evaluated and used to inform the development of a drug in its lifecycle. Go or no-go decisions either enhance drug development or stop poorly performing compounds sooner.

Q Do you believe that statistical analysis will be one of the biggest challenges faced in the field of clinical trial design?

Absolutely, because the data and the robustness of that data, is critical to our understanding. The biomarker, and the type of biomarkers we use, the value those biomarkers have, the very biomarkers we see in a patient group will tell us how we should use statistics to best address critical end points for a compound.

Q Your training & expertise is in the field of respiratory pharmacology and physiology – could you share your thoughts on where this field is heading?

The profiling of patient groups is going to be more important. Cystic fibrosis is one of these; the other one is idiopathic pulmonary fibrosis. Idiopathic pulmonary fibrosis is a late-onset disease of the lung, and there are no known cures. I see a greater use of precision medicine tools and companion diagnostic approaches to deliver a richer and more informed understanding of a compound's credibility. In addition, it is right that regulatory authorities encourage innovations in drug development to facilitate bringing compounds to the market sooner. While the industry is adapting, I see the need for further change and efficiencies in overall drug development given the cost and time associated with bringing precious drugs to market.

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