Session IV Roundtable Summary

In this guide

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What are the biggest research challenges for the microbiome field?

- The main concerns and challenges are centred around the limitations on conducting mechanistic work on each bacterial species present in the microbiome. Due to the complexity of all of the different bacterial species present, defining these species and their behaviour, metabolism and contribution to the microbiome environment will be important in carrying out further research.
- Another area of importance is to establish the endpoints for defining what constitutes an adverse effect from a microbiological and/or toxicological perspective. Establishment of these will give rise to more complex questions and interactions to be studied.
- From a regulatory perspective, an increase in the available scientific literature will affect how the safety of compounds and products is evaluated. These developments will have to be considered and will require a whole new array of expertise to evaluate safety.
- Trying to distinguish between causality, correlation or association.
- Defining standard parameters for a healthy and a pathogenic microbiome.
- Infrastructure: There is need for a stool biobank in which samples could be taken at the same time as blood samples.
- Standardisation of methods so that FMT results could be compared between different research groups. The results of sequencing in one laboratory should be the same as those in another laboratory so that the data can be compared.

What are the potential future innovative and disruptive ways of tackling microbiome function and host interaction?

- Members considered the rapidly developing use of AI in research and how an increase in databases with microbiological, metabolome and genomic data will utilise AI to process information and extract relevant trends or results. This will also go hand in hand with the expansion of AI use in research and industry, which needs to be harnessed, but in a controlled manner.
- After discussing a study presented in one of the talks about how the microbiome influence is greatest at < 3 years old, members considered what is the most significant variable in the composition of the microbiome. In particular, how much can diet, and external xenobiotics impact the composition of the microbiome after its initial establishment in early

childhood. If they can have a significant impact, which substances or factors have the most dramatic effect and is this what needs to be prioritised or do all potential factors have equal importance.
- Important to keep developing integrative multi-omics approaches to provide comprehensive and holistic understanding of host microbiome interaction.
- Advances in computational tools that could model the gut microbiome.

What are the current technologies, resources and skills in the field and the UK’s capabilities and capacity?

- There is limited access to laboratories and institutes that can accommodate aseptic technique studies and the use of human models in the same lab or institute.
- The importance of variety in animal and human models.
- Limitation of experts that are both computationally and lab-based trained as this is a crucial skill set to be able to interpret the kind of data produced in microbiome/metabolome-based research.
- Members highlighted the need for more AOPs to strengthen the evidence base and speculated that it is possible that a deviation in the microbiome may not be the adverse outcome in an AOP but rather one of the key events. Identifying the endpoints with which dysbiosis is associated is an important task for establishing AOPs.

What is the level of awareness and training available in the UK in this field?

- More training is needed for cross cutting issues.
- Better communication of the work being done across regulatory bodies and research.
- Take advantage of the national centres e.g. Quadram Institute.
- Still limited data, which cannot be used specifically, when conducting risk assessments, due to the absence of any concrete scientific advice or published guidance from the Scientific Advisory Committees. There was

particular emphasis from COT members that it would be critical to develop UK guidance to inform the public, scientific community and regulated community on how to consider the microbiome and its impact on human health.

Main themes

- Challenge in trying to distinguish between causality, correlation or association.
- Defining standard parameters for a healthy and a pathogenic microbiome.
- Infrastructure.
- Developing integrative multi-omics approaches can provide comprehensive and holistic understanding of host microbiome interaction.
- Increase in databases with microbiological, metabolome and genomic data will utilise AI to process information and extract relevant trends or results.