

Microbiome Forum Feedback

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Keynote

MICROBIAL CELLS
-100 TRILLION
(-70-90%)



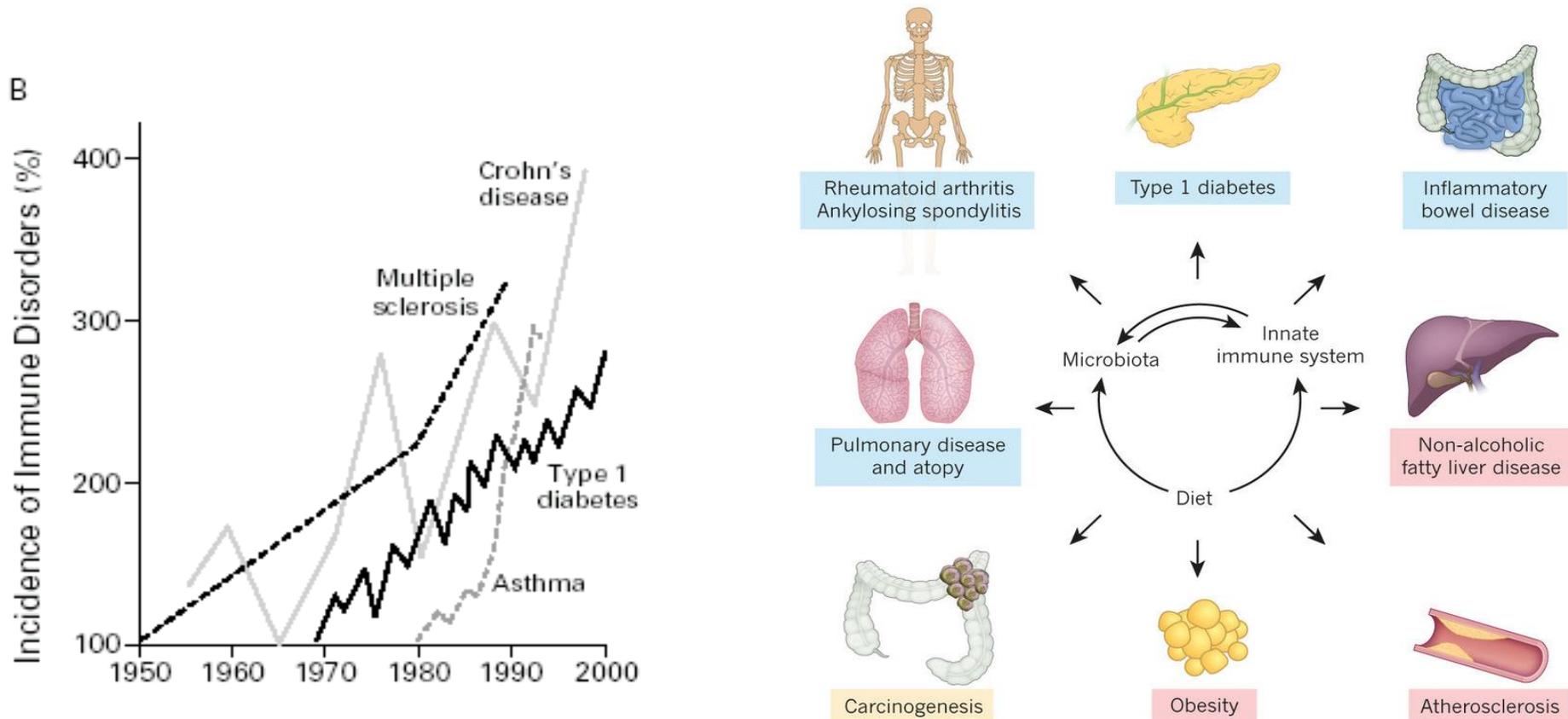
HUMAN CELLS
-30 TRILLION

The human intestinal microbiome is a neglected organ

- ✓ 100 trillion microorganisms ; more cells than the human body; up to 2 kg of mass!
- ✓ Interface between food and epithelium
- ✓ In contact with the 1st pool of immune cells and the 2nd pool of neural cells of the body

**An organism can function well
when all its organs function well**

The gut microbiome appears altered in many chronic diseases



Seven of the top 10 causes of death in 2010 were chronic diseases. Two of these—heart disease and cancer—accounted for nearly 48% of deaths in the US

Some scientific challenges that were identified

- Need for standardisation (building on what is already available)
- Characterisation and better definition of the microbiome: what is an healthy microbiome (and an “healthy” patient), the concept of “richness” as a parameter
- Study and link host response to microbiome changes and vice-versa (vicious circle vs virtuous circle)
- Better mechanistic understanding of microbiome alteration:
Interaction microbiome/treatment; different factors that influence microbiome (diet, smoking, life style changes...)
- Causal link between microbiome status and disease or disease risk factors
- What to analyse (bacteria, viruses..), pre-analytical and analytical challenges...

Some challenges that were identified from regulatory point of view

- Link product quality/composition to mechanism of action to potency/efficacy
- No harmonised view for classification of products containing live bacteria (medical products, devices, food supplements....)
- Different regulatory bodies at European level (EMA, EFSA) and at National level: lack of an harmonised regulatory approach
- Regulators do not have enough data yet , case by case approach, no guidelines yet
- Communication among regulators and regulators and innovators should be enhanced

Some challenges that were identified from different stakeholders

- Data sharing and data access as enablers of innovation: there are significant barriers to be overcome
- Patients need to be involved from the beginning and as partners, they need to be properly informed to be motivated to participate: Importance to listen to the patients
- Define the “perimeter” of a middle area where both food industry and pharma can work together and generate value
- Prepare the field to the patient pathways of tomorrow
- The microbiome field is moving very fast: importance to keep up with the science
- Lots of investments and resources have been made: importance to capitalise on this
- De-risk product development

Do not forget the animals: beyond the mouse

Need to also involve the digital industry

Incentives to collaborate and create a partnership

- Different industry sectors, food and pharma, have complementary experience and expertise, tools and methods that could be shared and leveraged to common benefit
- There is significant new knowledge and important assets (databases, biobanks, standards) in the public space that could be taken to the next level by the interaction with industry
- Regulators need data to move regulatory science in order to enable new products reaching the market
- Create an open innovation space to de-risk biotech activities in the field
- Patients need new treatments that have been developed in partnership with them to ensure these will have a real impact on quality of life



IMI could have a clear role in empowering the field

Four potential themes were discussed

- Large longitudinal studies with open access to metadata
- Bio-informatics solutions for strain level identification and analysis of hypothetical genes
- Bio-banks of identifiable species with metadata, reference methods and standards
- Translational studies addressing microbiome causality in human health and disease

Developing alliance between food and drug areas to reach a sustainable healthcare system.

Microbiome is interfaced in the middle and it's an opportunity that cannot be missed.

