Theme 4: Translational Studies Addressing Microbiome Causality in Human Health and Disease

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Acknowledgment

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- Daniel Peterson, Eli Lilly
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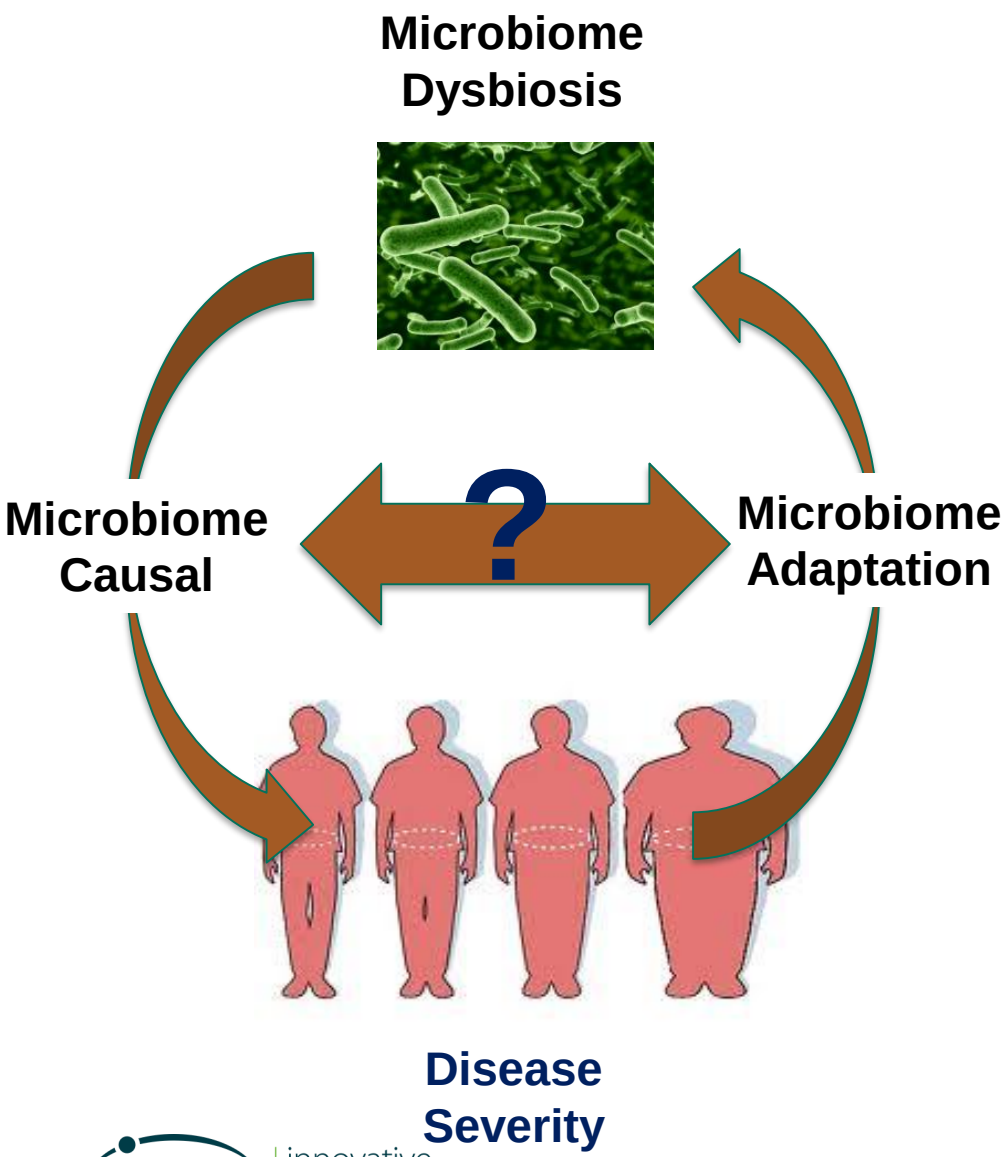
Background: Microbiome-Disease Causality



- Are changes in the microbiome causing disease or merely microbial adaptations to the disease environment?
- By what mechanism does the microbiome affect the disease state?
- What human host genes / pathways link microbiome with disease pathology?
- Can microbiome manipulation reverse a disease phenotype?
- Is the proposed microbiome therapy superior to current standards of care?

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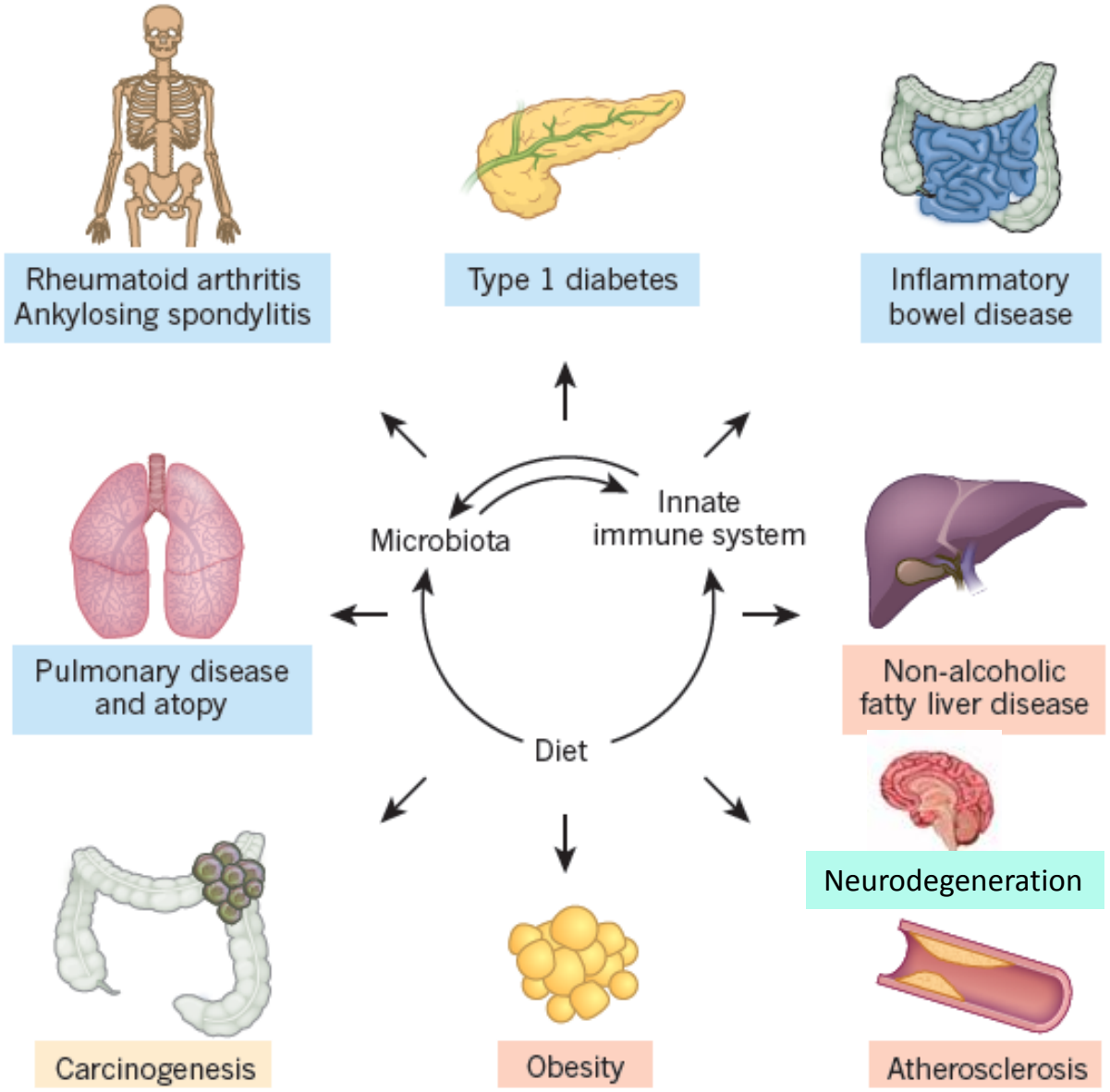
Microbiome, Immunity and Inflammation

- Microbiome dysbiosis and dysregulation of immune function is thought to underlie multiple diseases
- Mapping the dynamics of the host-microbiome interactions is essential to confirm disease causality
- Well-designed studies of the systems biology behind human host response to microbiome changes during disease are urgently needed



Thaiss et al. 2016 Nature. 535:65

Deliverables

- Robust testing of mechanistic hypotheses regarding the microbiome's role in a specific human disease or health condition for future drug, vaccine or consumer product target discovery:
  - Human clinical trials or exploratory medicine studies involving treatment with microbiome modulators are highly encouraged.

- Generation of well-powered, longitudinal, high dimensional 'omics datasets and computational models of both the microbiome and human/mammalian host response.

- New tools for modulating and manipulating the microbiome *in vivo* or *ex vivo*, such as small molecules, prebiotics, probiotics, etc. which will be available to the wider research community.

Project Examples

- Longitudinal studies of microbiome and human host response in specific disease areas (i.e. inflammatory diseases, metabolic diseases, infectious disease, cancer, autoimmune disorders, etc.)

- Longitudinal studies of microbiome and human host response to life-style / life history changes (i.e. nutritional regimens, aging, vaccinations, exposure to environmental allergens, etc.).

- Longitudinal studies of microbiome and human host response to specific interventions (i.e. small molecule drugs, biologicals, vaccines, nutritional supplements, probiotics, prebiotics, etc.).

- Studies should prove or disprove existing or new hypotheses about microbiome role in human health.

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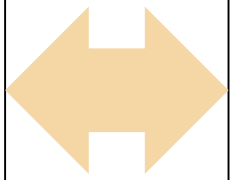
The Need for Public-Private Collaborative Research

Public Institutions

- Deep and broad scientific knowledge
- Innovative technology
- Advanced computational tools and analytics
- Preclinical studies in human relevant models
- Access to bacterial strains
- Design and execution of clinical studies



Industry

- Expertise on basic science to medicine translation
- Innovative clinical trial design
- Access to existing or planned clinical trials to add-on host-microbiome ‘omics analyses
- Statistical, computational, drug development, other expertise
- Tools for manipulating the microbiome (i.e. small molecules, biologicals, etc.)

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Discussion

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