Eliminating Regulatory Hurdles through Pre-Competitive Research, Databases, and Standards

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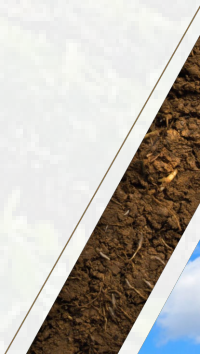
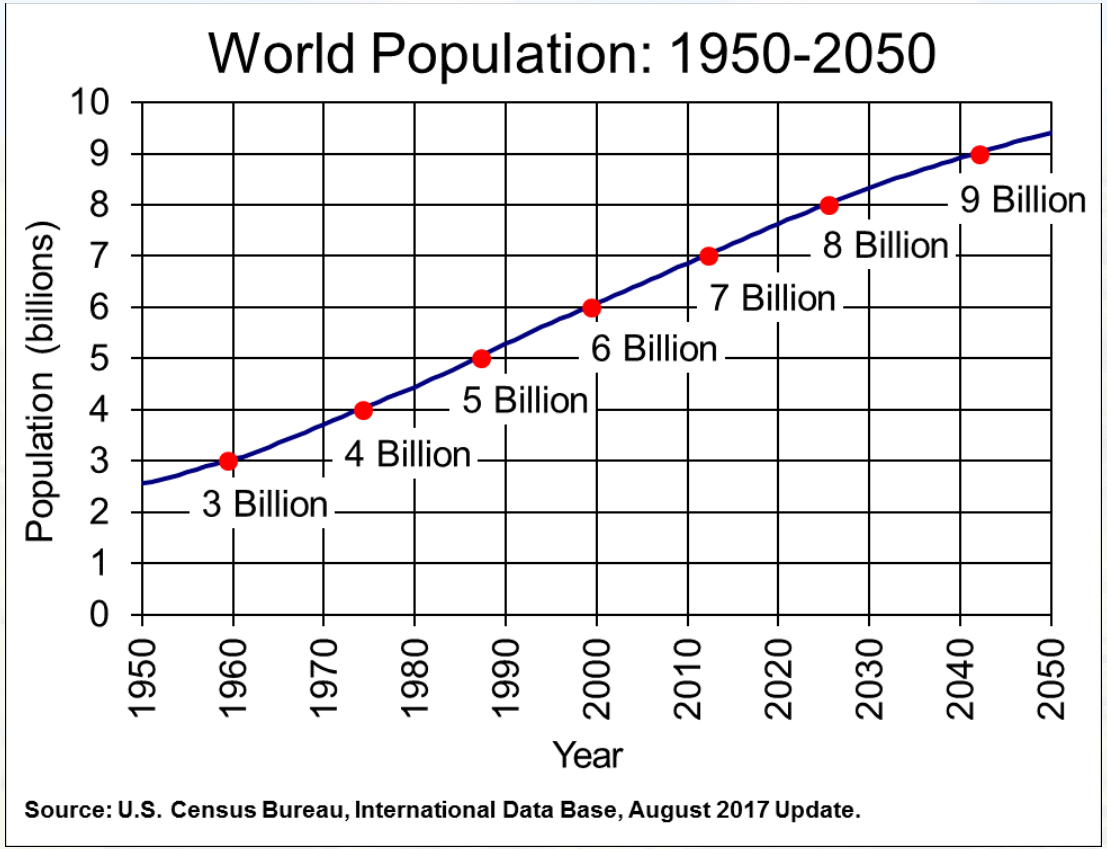
24 February 2020

Defining Microbiome Datapoints Workshop

Raleigh, North Carolina



The Challenge



Realities:

- **Insufficient productivity growth**
- **Limited land**
- **30 Growing Seasons**

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Holy Grail for Plant Production

To understand, predict, and control emergent phenotypes within specific sites for the sustainable production of food, feed, and fiber

How do we get there?

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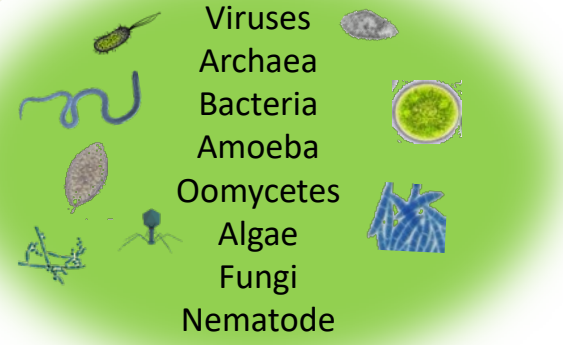
Phytobiomes: Complex Systems of Plant-based Agriculture

Climate, Weather, Water

"Biomes": Site specific environments



Microbiomes and Macroorganisms/Macrofauna

Arthropods, Other Animals and Plants

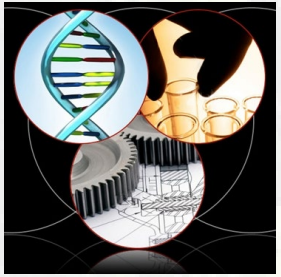
Why can we embrace this now?

All influenced by Management Practices

Technological Advances

- Omics-enabling technologies and data
- Advances in computational science
  - Machine learning, deep learning
  - Network analyses
  - Predictive analytics
  - Quantum computing
- Precision Agriculture
  - Variable rate technology…seeding & input
  - Unmanned Aerial Systems (UAS)
  - Soil, plant, & weather sensors
  - Robotics
- Convergence science
  - Systems level methods
  - Move from multi- to trans-disciplinarity

➢ **For plants: Phytobiomes approach**



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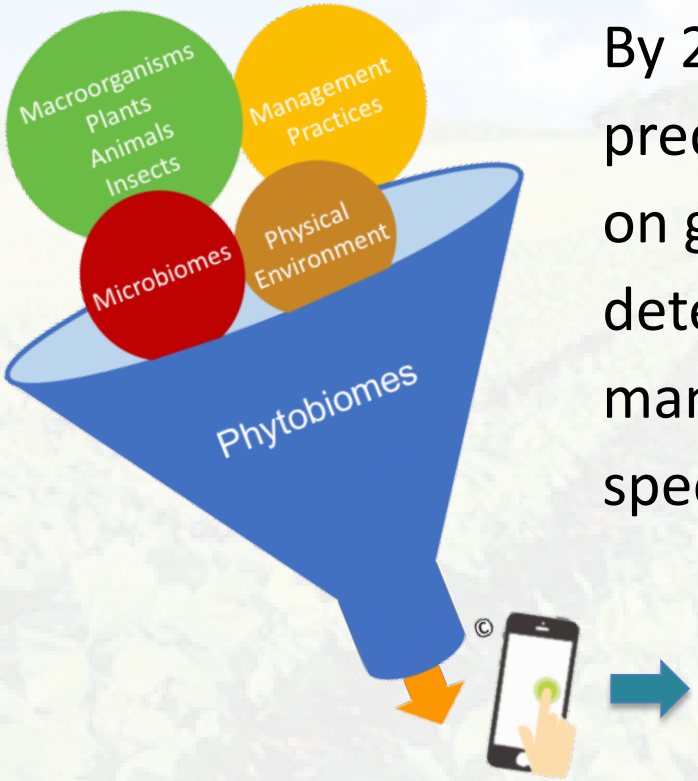
Phytobiomes Alliance Vision



By 2050, all farmers have the ability to use predictive and prescriptive analytics based on geophysical and biological conditions for determining the best combination of crops, management practices, and inputs for a specific field in a given year.

- **Management practices**
- **Seeds and seeding rates**
- **Biological products**
- **Microbes and microbiomes additions**

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Phytobiomes Alliance

Our **mission** is to establish a science and technology foundation for site-specific, phytobiome-based enhancement of sustainable food, feed, and fiber production

Phytobiomes: Major Research Gaps

Microbiomes and Macroorganisms/Macrofauna

Climate, Weather, Water

Arthropods, Other Animals and Plants

Management Practices: Precision Agriculture

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Short-term Research Priorities

- Enhance understanding of the interactions between plants, microbiomes, and other components of phytobiome systems
- Databases that support correlation and network studies of site-specific and temporal geophysical and biological data
- Research and develop stabilization methods for Gram-negative bacteria for large quantities of seed with on-seed stability of 120 days
- Develop methods for cryopreservation of entire microbial communities

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Short-term Regulatory Science Priorities

- Consensus risk assessment methods to establish the safety and efficacy of microorganisms
- Genome sequence-based classification system and risk prediction methods for microbes
- Databases of public & private microbial genome and metagenomic sequences (WGS, 16S, ITS)
- Standards, protocols, check-lists (minimum information, sampling, reference datasets, regulatory requirements, WGS quality…)
- Census of microbes by state, province, region, and country
- Cost-effective in-field sequencing platforms
- Machine learning methods (e.g., NLP) for scientific literature (biology, mode of action, stability, related studies….)

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Longer-Term Regulatory Science Priorities

- Artificial intelligence methods for microbial and microbiome annotation and gene prediction
- Science to support commercialization of microbial communities that include uncultured microbes and genetically engineered microbes
- Other artificial intelligence, machine learning, and deep learning approaches which could support research, regulatory review, and commercialization of microbes, microbial communities, and genetically engineered microbes
- Models that can be used to substitute field trials while taking into consideration the effect of the entire phytobiome

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Areas of Progress

- Genome sequence-based classification system and risk prediction classification system for microbes
- Microbe sequence database that includes phenotypic data
- Draft standards, protocols, check-lists (minimum information, sampling, reference datasets, regulatory requirements…)

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Alliance LINS Project: Whole Genome Sequence-Based Classification & Identification Platform

Model: *Ralstonia solanacearum*

Database of sequences coupled to pathogenicity data

Precisely circumscribe the strains that should be designated as "Select Agents"

Objective: Enable rapid and precise taxonomic identification of microbes

Expand model to other agriculturally relevant bacteria

Expand to include plant-associated fungi

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Risk Prediction Classification (Submitted)

- Develop a “risk prediction” method for beneficial plant bacteria
- Initial focus on *Bacillus, Pseudomonas*, and *Burkholderia* with plant growth promoting activity and biocontrol activity
- Objectives include:
  - ✓ Developing a precise genome sequence-based classification and genome sequence-based phylogenetic trees of the strains
  - ✓ Identifying genetic markers associated with beneficial and pathogenic strains belonging to the genus *Bacillus*
  - ✓ Precisely circumscribe strains that are, and are not, pathogens and plant beneficials

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Database for rapid assessment of geographic distribution of microbes

- Expand/create database to include WGS, 16S, ITS, metagenomic sequences coupled with geographic metadata
- Controlled vocabulary for phytobiome-associated metadata
- Identify best practices, reference materials, and standards for characterizing phytobiome microbes

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Community-driven Metadata Standards for Agricultural Microbiome Research

- Need for agriculture-specific metadata standards
- Propose a list of “required” and “desirable” metadata categories and ontologies essential to be included in a future minimum information metadata standards checklist for describing agricultural microbiome studies

First Look
7 January 2020

AGRICULTURAL MICROBIOMES RESEARCH COORDINATION NETWORK

Dundore-Arias, et. al. https://doi.org/10.1094/PBIOMES-09-19-0051-P

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Proposed Metadata Categories for Future Minimum Information checklist for Agricultural Microbiome Studies (MIxS-Ag)

- Site or location context
- Sample type and description (soil/root associated vs aboveground plant-associated)
- Sample collection
- Sample processing
- Climate
- Management practices history and abiotic characteristics

➢ **Alliance Next Steps: Input from our scientific coordinating committee, industry, EU projects and groups, other interested stakeholders and governmental entities**

Dundore-Arias, et. al. https://doi.org/10.1094/PBIOMES-09-19-0051-P

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Phytobiomes Conference 2020

1-4 December 2020

Denver, CO, USA

www.phytobiomesconference.org

Main Scientific topics

- Plant fitness
- Microbial community assembly and function
- Network analyses within the phytobiome system
- Modeling
- Data – framework, tools and resources, big data
- Genetic linkages
- Engineering to improve carbon sequestration
- Interactions within phytobiomes for abiotic stress
- Engineering microbes and microbial communities
- Precision agriculture
- Controlled environment agriculture
- Fertilizer, nutrient, and chemical input efficiency
- Product development
- Regulatory requirements
- Greenhouse & Field trials
- Industry research needs

International Alliance for Phytobiomes Research Sponsors

Thank you for your attention!

www.phytobiomesalliance.org