

Athira Sudhakaran is a Bio-Statistician at Genpro Life Sciences with nearly 3 years of experience in the Clinical Domain and has a Masters in Biostatistics. She has worked on the safety and efficacy analysis for over 15+ studies and is experienced in niche areas like Microbiome Analysis. Specifically interested in implementing her core Statistical Skills into the Design of a Clinical Trial. Personal hobbies include photography and gardening. Find her on LinkedIn at

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Limna Salim is a B-Tech Graduate currently working as the Manager of Statistical Programming at Genpro Life Sciences with nearly 5 years of experience in multiple industries. She was part of safety and efficacy analysis for several studies and was part of multiple FDA Submissions along with an experience in CDISC Standards. Interested in exploring similar technologies like Python/R and aspires in bringing along multiple tools that helps in making the life of Statisticians much simpler. Personal hobbies include travelling and dancing. Find her on LinkedIn at

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Statistical Analysis and Visualization of Microbiome data in Clinical Trials

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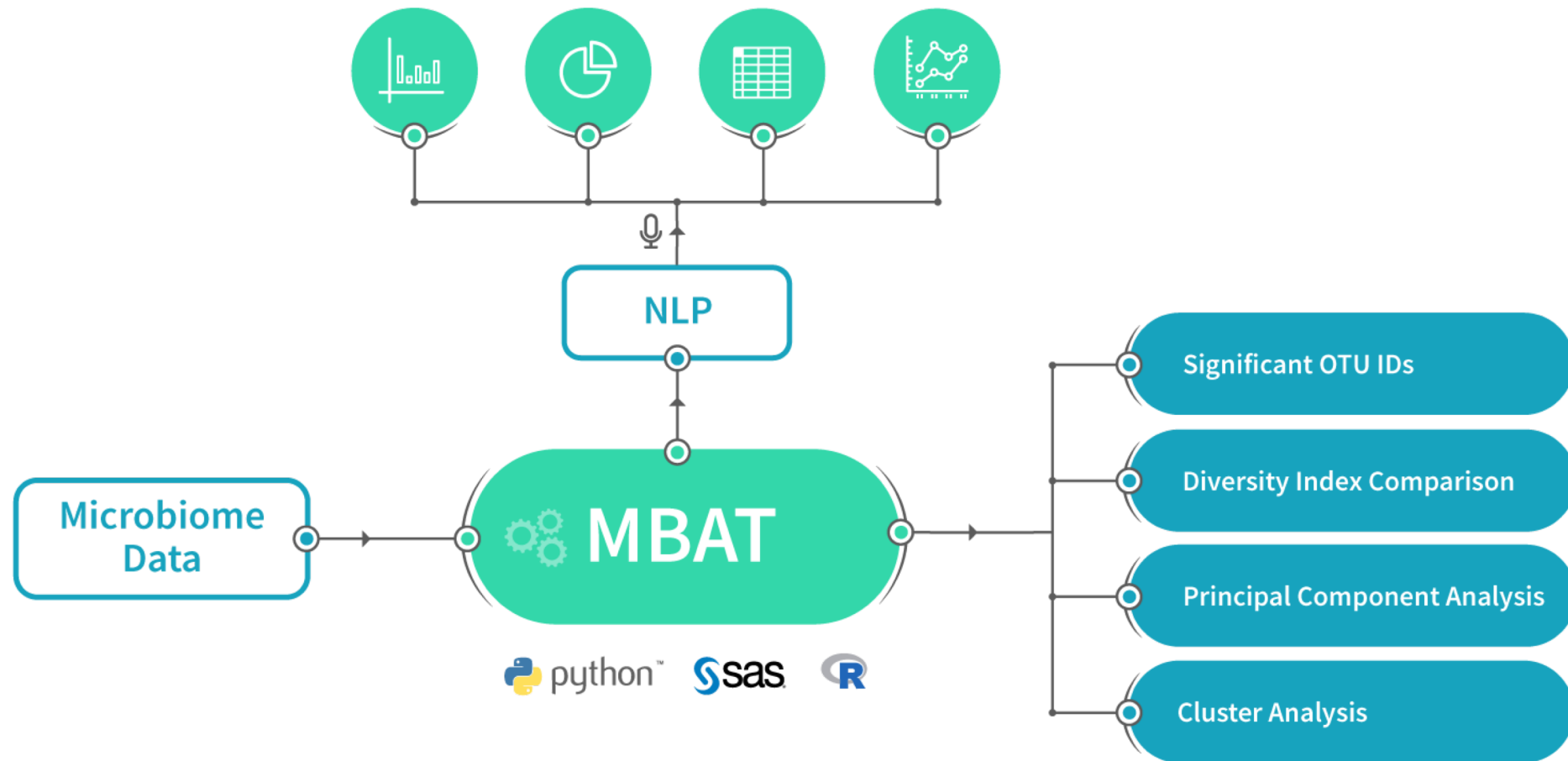
Microbiomes

- ▶ The human microbiota is the aggregate of microorganisms that resides on or within any of a number of human tissues and biofluids.
- ▶ The human microbiome refers specifically to the collective genomes of resident microorganisms.

Microbiome in Clinical Trials

- ▶ Radical changes in Microbiome research has revealed a wide array of important roles that the microbiota play in human and animal health.
- ▶ Issues faced are
 - Handling of large complex data
 - New methods and models suitable for analyzing microbiome data.

MBAT(Microbiome Analysis Tool kit)

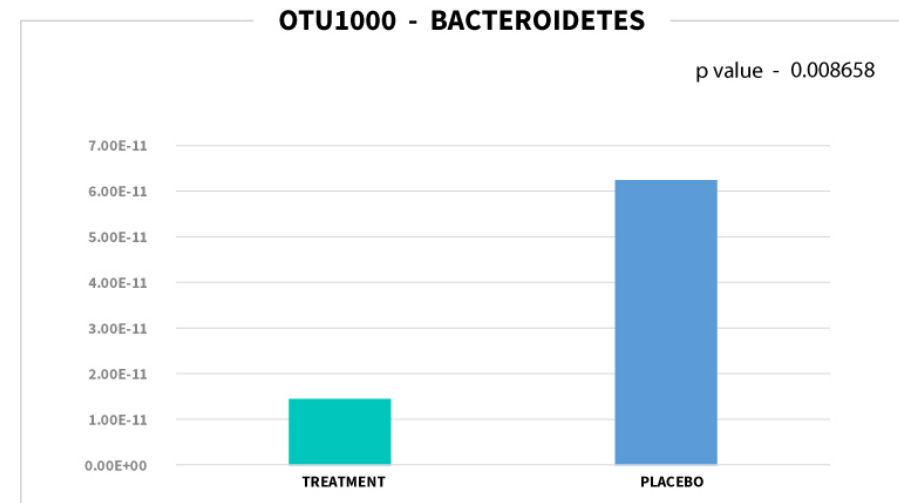


WHY MBAT?

- ▶ Analyze Microbiome data using interactive visualization
- ▶ Possibilities of using SAS to put together an analysis framework for microbiome data
- ▶ Five different statistical/machine learning methods to understand microbiome data structure and analyze

SIGNIFICANT OPERATIONAL TAXONOMIC UNIT

- ▶ Identifying
 - Relevant statistical test
 - Individual OTU ids which are significantly different between the groups
- ▶ Graphical representation of the distribution of each significant OTU id

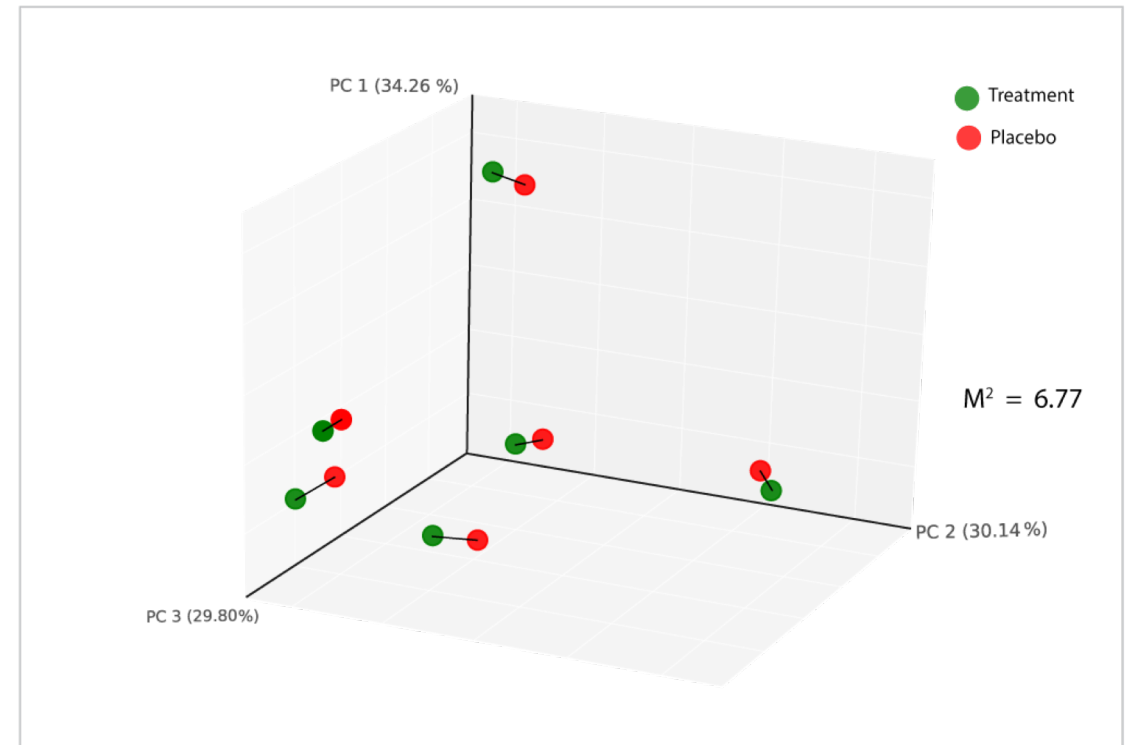


COMMUNITY CHARACTERISTICS

- ▶ Richness – The number of species in each sample
- ▶ Abundance – Relative representation of a species
- ▶ Dominance – Degree to which a taxon is more numerous than its competitors
- ▶ Diversity index – Weighted average of the proportions of each species present

COMPARISON BASED ON THE DISTANCE MATRIX

- ▶ Comparison of microbiome data for each subject using distance matrix principal coordinate analysis
- ▶ Rotating, scaling, and translating coordinate set to minimize the distances between the points



CLUSTER ANALYSIS– MINIMIZING BIAS

- ▶ Unsupervised learning analysis
- ▶ To assess whether samples can be clustered into groups representing the two study product groups
- ▶ K-means clustering to cluster the samples within each treatment group
- ▶ Assess the accuracy with which the clusters recapitulate the treatment groups

Tools and Technologies

- ▶ MBAT (Microbiome Analysis Tool kit) is a web based application which will combine the features of
 - SAS
 - R
 - Python
 - Rasa NLU
 - Angular JS

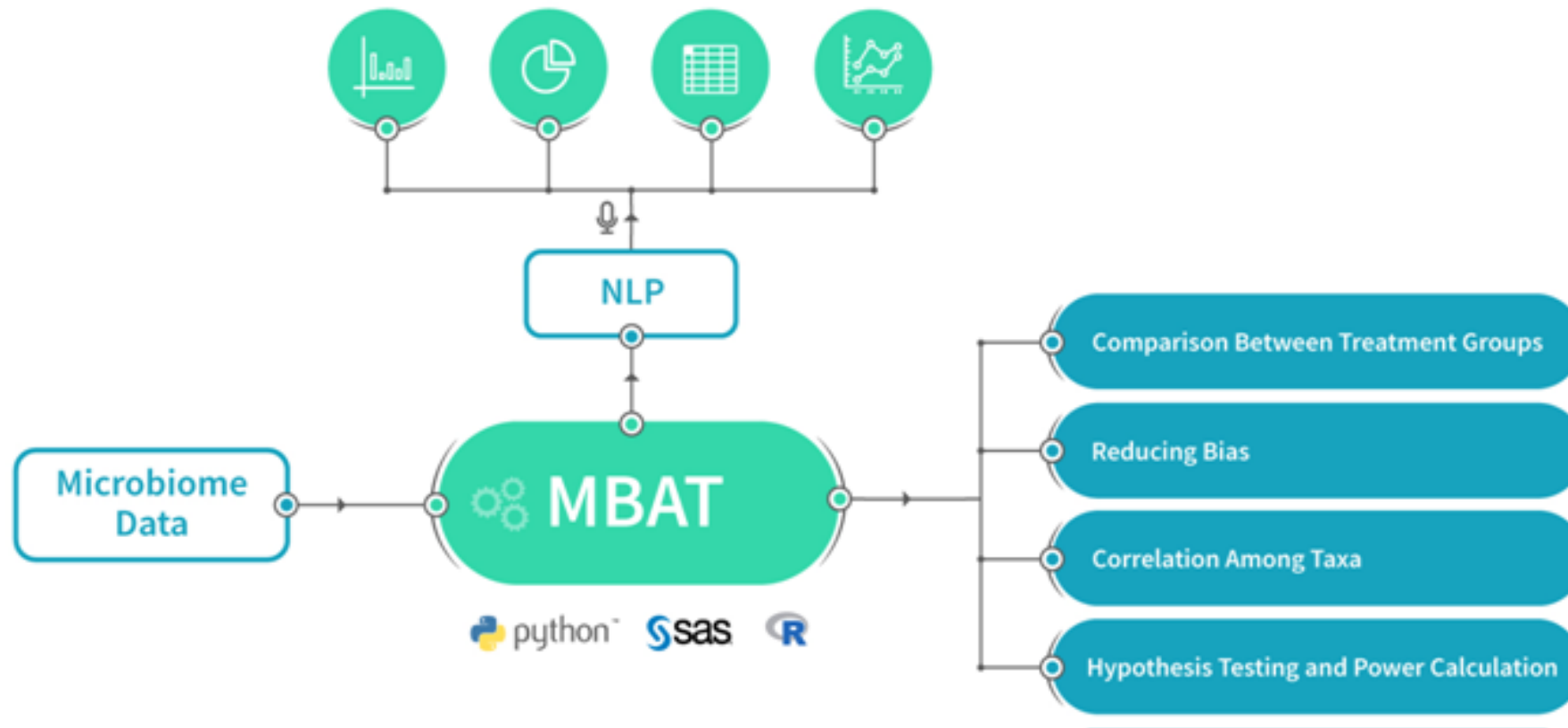
Data Sources and References

- ▶ MINE: Maximal Information–based Nonparametric Exploration
<http://www.exploredata.net/Downloads/Microbiome-Data-Set>
- ▶ HMP QIIME project BIOM format compatible
<https://groups.google.com/forum/#!topic/qiime-forum/Cc80yDBXDfg>
- ▶ Functional Redundancy–Induced Stability of Gut Microbiota Subjected to Disturbance.
<https://www.ncbi.nlm.nih.gov/pubmed/26996765>
- ▶ The gut microbiota—masters of host development and physiology.
<https://www.ncbi.nlm.nih.gov/pubmed/23435359>
- ▶ New approaches for bacteriotherapy: prebiotics, new–generation probiotics, and synbiotics.
<https://www.ncbi.nlm.nih.gov/pubmed/25922396>
- ▶ Distal airway microbiome is associated with immune regulatory myeloid cell responses in lung transplant recipients.
<https://www.ncbi.nlm.nih.gov/pubmed/28756121>

Future Plans

- ▶ Add more statistical tests
- ▶ Make it commercially available
- ▶ Refine NLP based data visualization
- ▶ Tie up with Academic and Research Institutions
- ▶ Collaboration with pharmaceutical companies

Future Plans



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