“Getting Ahead of The Curve for Early Diagnosis of Preventable Diseases”

The Narrative

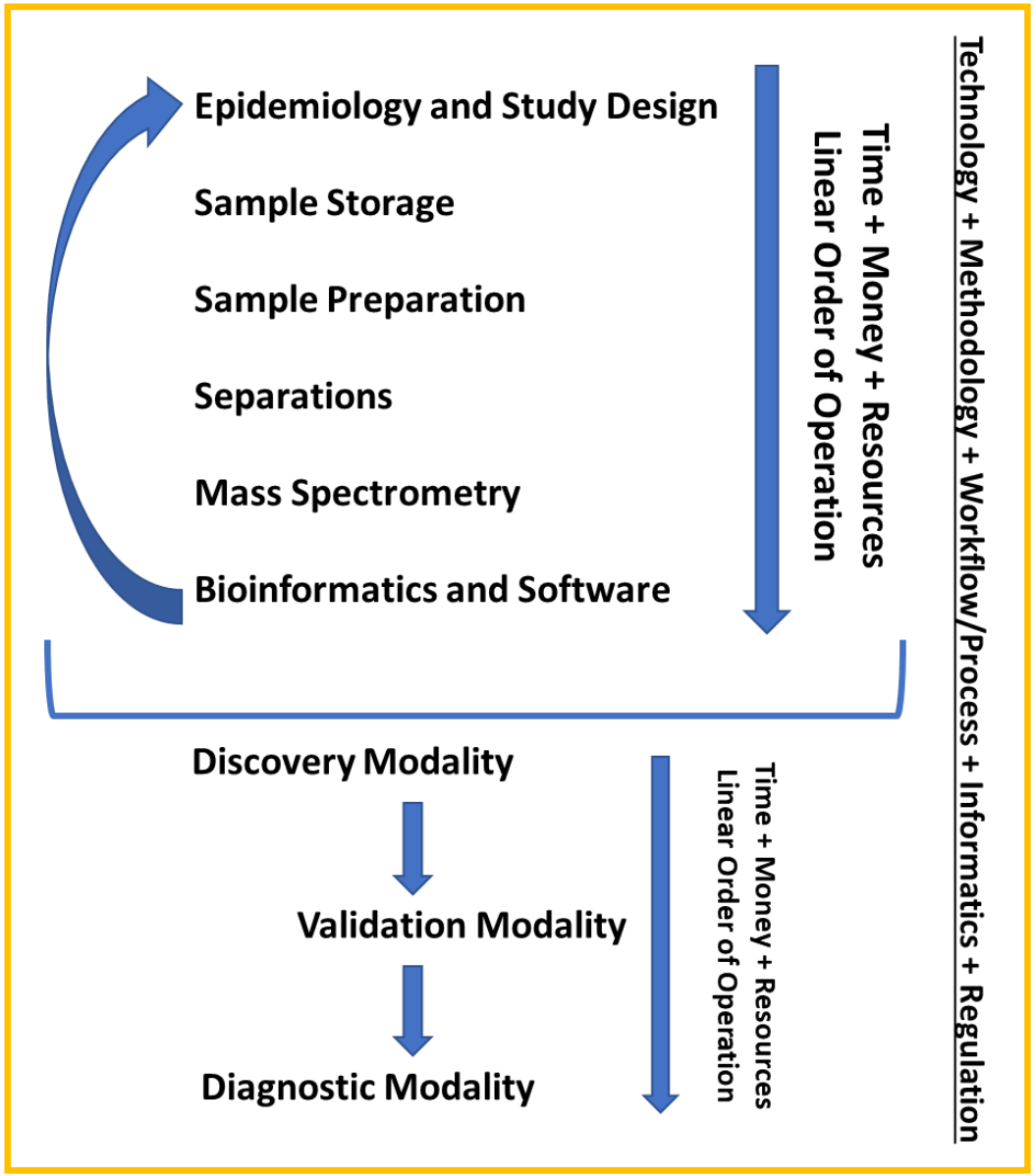
- Patient Centric: The general population simply does not understand the difficulty of biomedical research - education.
- Doctor Centric: Healthcare is competitive an drive costs and development.
- Clinical Diagnostic Centric: Regulatory Barriers to bring new test to market. Time and cost can be prohibitive
- Method Validation Centric: Translation of metabolomics pilot studies (Biomarker and MOA) do not always work and sometimes lack funding.
- Metabolomics Discovery Centric: Lots of success and moving towards improved standards across stakeholders in the field.
- Do we have most of the tools we need to accelerate these tests?

The Consortium and its tractability

Three “Sets” of Stakeholders	**Role, contribute, benefit**
- (A) Biomarker Discovery and Research - (B) Validation of New Markers or Test - (C) Finial Clinical Diagnostics Bed-Side -- *Standardization of Key Technical Aspects and Harmonization across labs.*	- (A) Standards and Workflows - (B) Follow Regulatory Guidance and translate the findings. - (C) Economics of the final test and Harmonization

CPSA Metabolomics 2019 - Prepared By: Jeremiah D. Tipton -- BioTech & OMICSx Solutions, LLC and Helena Svobodova -- New Objective, Inc.

“Getting Ahead of The Curve for Early Diagnosis of Preventable Diseases”



Opportunity

- The Top Process is the Typical Clinical Research Metabolomics experiment – we have some standard protocols and methods in place. Now work for some sort of harmonization.
- Think about patient outcomes when designing metabolomics experiments. Final diagnostic tests for neglected diseases should start with Clinical Metabolomics experiment for standardization.
- Regulatory Process to develop test following the discovery of a biomarker or panel is cost and time prohibitive.
- Benefits from full pipeline management – Discovery to Diagnostics with reduced regulator cost and time.
- Benefit for central source that monitors the pipelines; not just the validation and diagnostic modalities.
- New Born Screening is a great example and we can learn from the success.
- Create a system to monitor performance across tests.
- Benefit to working on neglected/terminal diseases

“Getting Ahead of The Curve for Early Diagnosis of Preventable Diseases”

Risk/Benefit Calculations	- Difficult to Harmonize Metabolomics because it is often a research tool. - Economics of Clinical Research Metabolomics Experiments and competition across labs creates a difficult situation for harmonization. - Regulatory Rules, Cost, and Time to market is often inhibitory for bringing key tests to market. Are we lacking expertise in the Validation Modality. - Many workflows for discovery and validation are difficult and need expert users. Final diagnostic test needs to be easy to use. - We are in paradigm shift, are people ready for the shift – more education. - Healthcare is competitive. Doctors, Patients, and Insurance Companies want the cheapest tests.