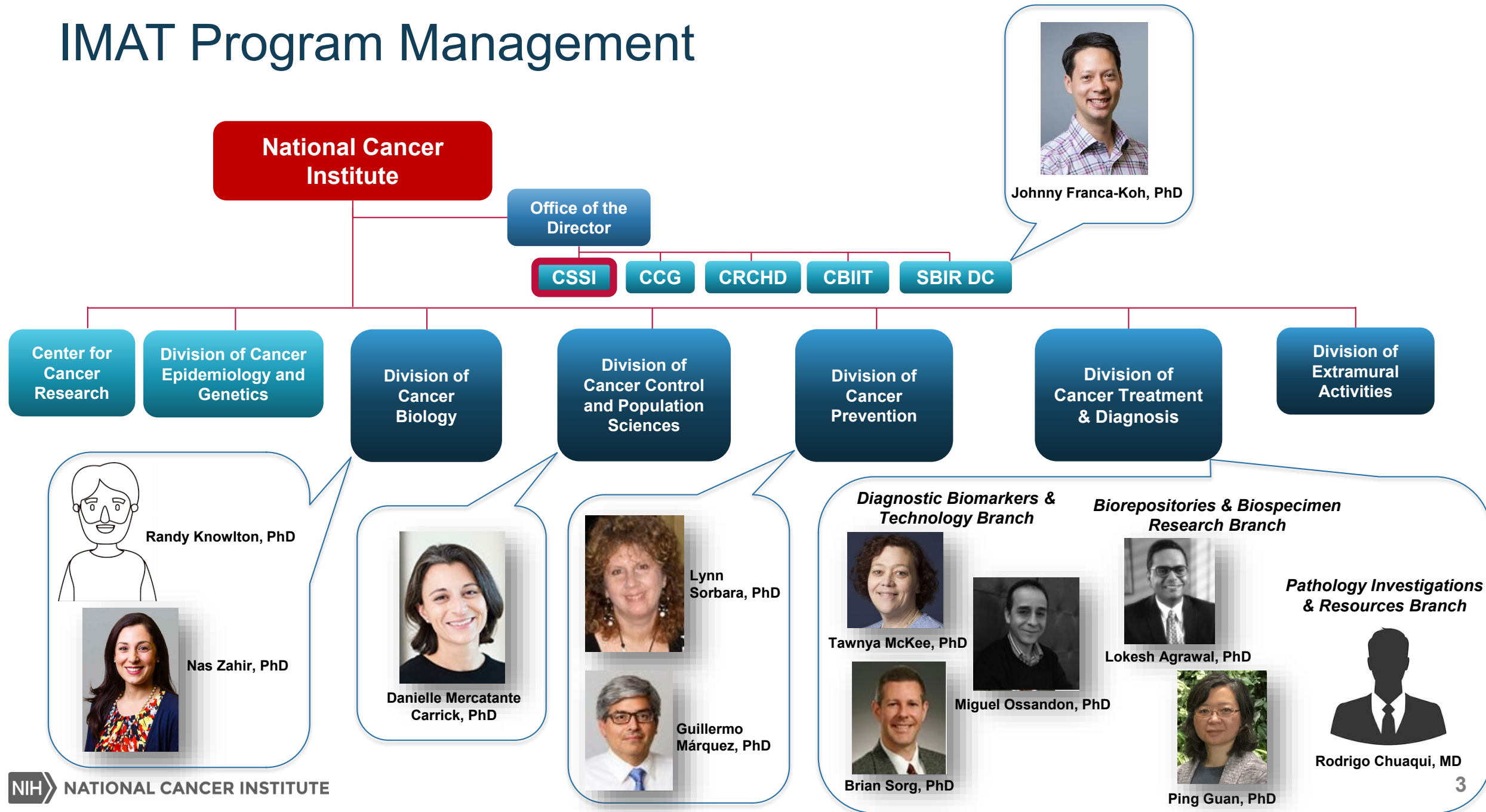# 2018 PI Meeting Agenda

- Molecular Pathway Tools

- New Approaches for Sample Preparation and Preservation

- miRNA Detection Approaches

- Technologies to Improve Drug Discovery and Development

- Next Generation Clinical Diagnostic Technologies

- Cancer Modeling

- Imaging Probes

- Single Cell Analysis Technologies

- Advances in Mass Spectrometry

119 Active Projects (66 R21 & 53 R33)
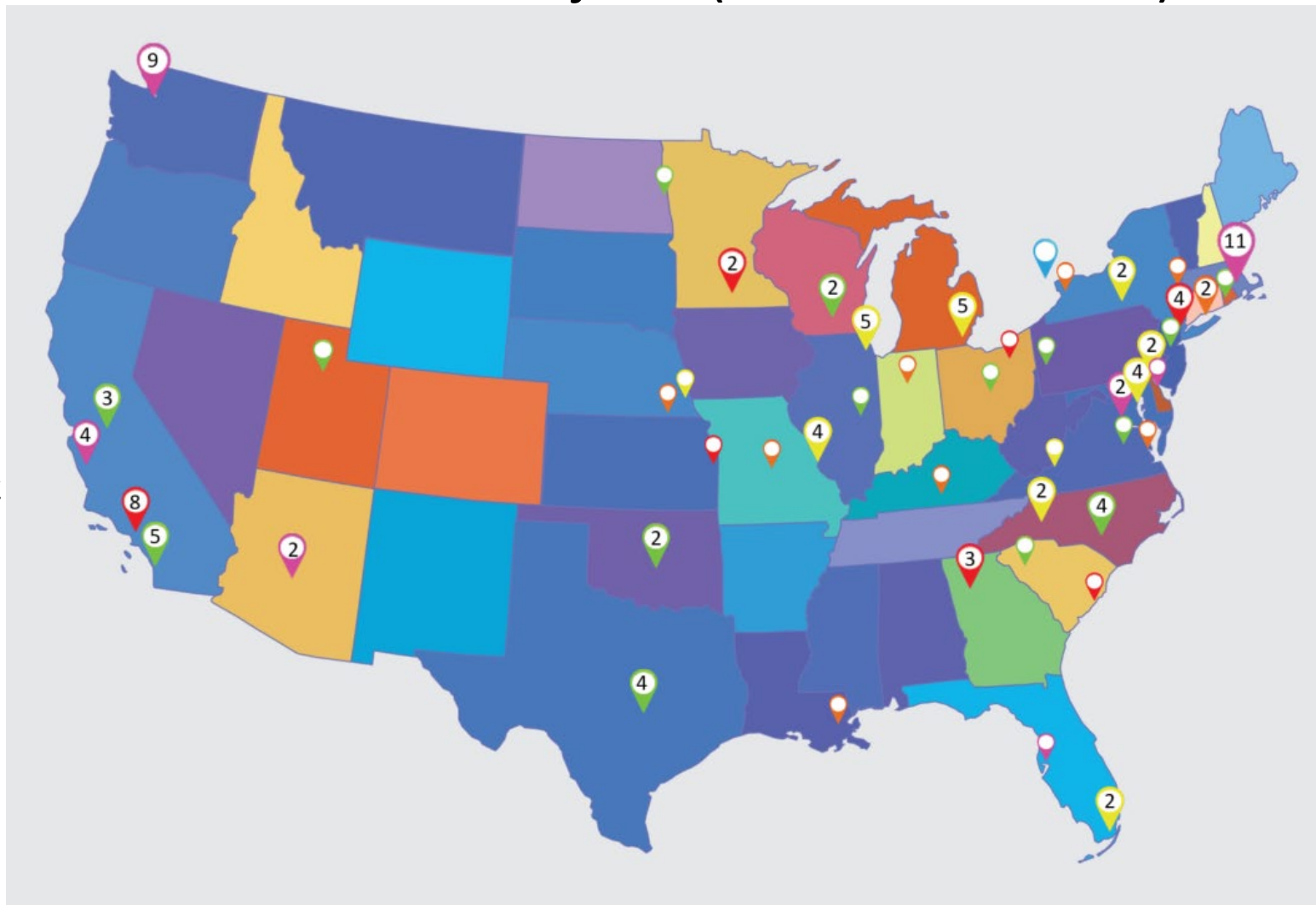
IMAT Program Management

National Cancer Institute

Johnny Franca-Koh, PhD

Office of the Director

CSSI · CCG · CRCHD · CBIIT · SBIR DC

Center for Cancer Research · Division of Cancer Epidemiology and Genetics · Division of Cancer Biology · Division of Cancer Control and Population Sciences · Division of Cancer Prevention · Division of Cancer Treatment & Diagnosis · Division of Extramural Activities

Randy Knowlton, PhD

Nas Zahir, PhD

Danielle Mercatante Carrick, PhD

Lynn Sorbara, PhD

Guillermo Márquez, PhD

Diagnostic Biomarkers & Technology Branch

Tawnya McKee, PhD

Miguel Ossandon, PhD

Brian Sorg, PhD

Biorepositories & Biospecimen Research Branch

Lokesh Agrawal, PhD

Ping Guan, PhD

Pathology Investigations & Resources Branch

Rodrigo Chuaqui, MD
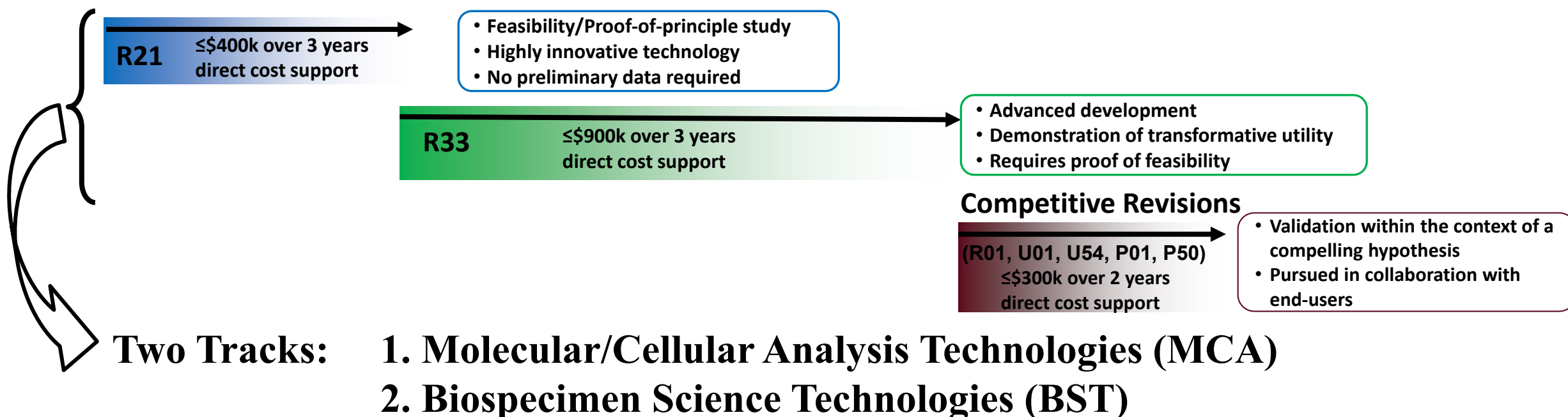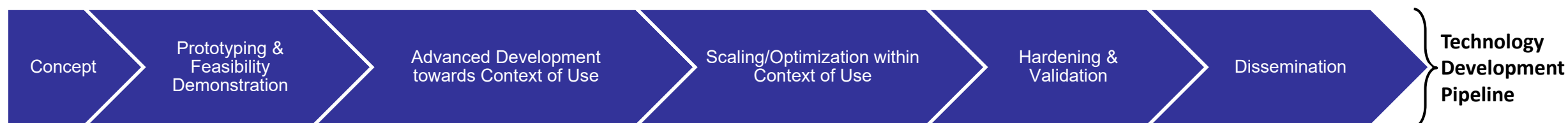
Innovative Molecular Analysis Technologies (IMAT) Program

INNOVATIVE MOLECULAR
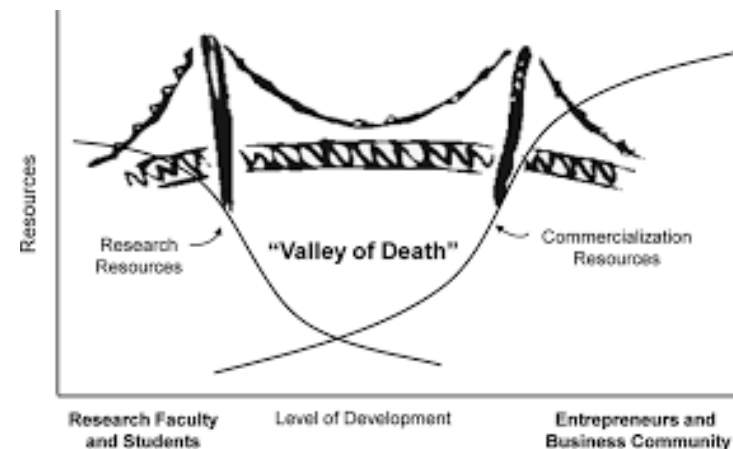ANALYSIS TECHNOLOGIES
IMAT

Program Mission:

To support the development, maturation, and dissemination of novel and potentially transformative next-generation technologies through an approach of balanced but targeted innovation in support of clinical, laboratory, or epidemiological research on cancer.

Concept	Prototyping & Feasibility Demonstration	Advanced Development towards Context of Use	Scaling/Optimization within Context of Use	Hardening & Validation	Dissemination

Technology Development Pipeline

R21 ≤$400k over 3 years direct cost support
- **Feasibility/Proof-of-principle study**
- **Highly innovative technology**
- **No preliminary data required**

R33 ≤$900k over 3 years direct cost support
- **Advanced development**
- **Demonstration of transformative utility**
- **Requires proof of feasibility**

Competitive Revisions

(R01, U01, U54, P01, P50) ≤$300k over 2 years direct cost support
- **Validation within the context of a compelling hypothesis**
- **Pursued in collaboration with end-users**

Two Tracks:
1. **Molecular/Cellular Analysis Technologies (MCA)**
2. **Biospecimen Science Technologies (BST)**

Technology Development Pipeline

| Concept | Prototyping & Feasibility Demonstration | Advanced Development towards Context of Use | Scaling/Optimization within Context of Use | Hardening & Validation | Dissemination |

R21 — ≤$400k over 3years (direct costs)

R33 — ≤$900k over 3years (direct costs)

Resources — Research Resources — "Valley of Death" — Commercialization Resources

Research Faculty and Students — Level of Development — Entrepreneurs and Business Community

SBIR & STTR

I-Corps™ at NIH

- Intensive *entrepreneurial immersion* course aimed at reducing commercialization risk
- Emphasizes **reaching out to customers to test hypotheses about the need** and market for the technology being developed.

GCMI
Global Center for Medical Innovation

- GCMI establishes a specific scope of work and detailed project plan with each team.
- Along the way, projects receive guidance and access to GCMI's resources and network.

Competitive Revision RFAs

(R01,U01,U54,P01,P50,U2C)
≤$300k over 2 years
(direct costs)

- Validation within the context of a compelling hypothesis
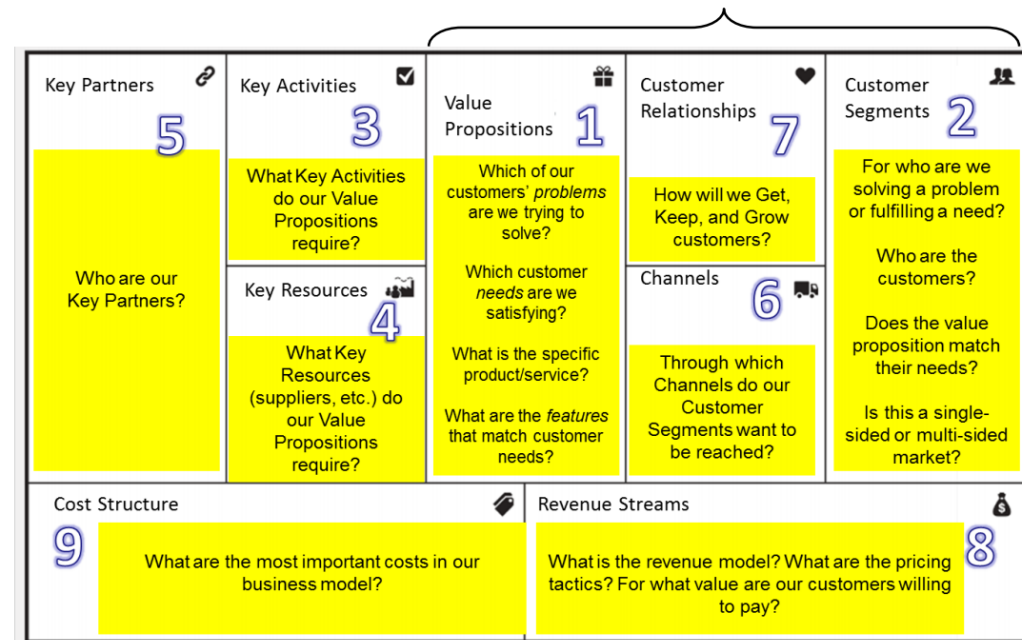- Pursued in collaboration with end-users

1.Business Model Canvas

"Product-Market Fit"

Key Partners 🔗	Key Activities ☑	Value Propositions 🎁	Customer Relationships ❤	Customer Segments 👥
5	3	1	7	2
Who are our Key Partners?	What Key Activities do our Value Propositions require?	Which of our customers' *problems* are we trying to solve? Which customer *needs* are we satisfying? What is the specific product/service? What are the *features* that match customer needs?	How will we Get, Keep, and Grow customers?	For who are we solving a problem or fulfilling a need? Who are the customers? Does the value proposition match their needs? Is this a single-sided or multi-sided market?
	Key Resources 🏭 4		Channels 🚚 6	
	What Key Resources (suppliers, etc.) do our Value Propositions require?		Through which Channels do our Customer Segments want to be reached?	

Cost Structure 🏷	Revenue Streams 💰
9	8
What are the most important costs in our business model?	What is the revenue model? What are the pricing tactics? For what value are our customers willing to pay?

2.Entrepreneurial Immersion Course

- *3-Day kick-off event*
- *6 weekly web classes*
- *Each team is expected to conduct over 100 interviews over 8 weeks*
- *2-Day Lessons Learned close-out*

Comprehensive medical device innovation center, dedicated to accelerating development, building businesses, and improving health.

GCMI collaborates with partners that provide input and become part of the team to establish milestones

Intake	Accelerate	Launch
Proven vetting process	Measured, milestone-driven, high-touch, collaborative approach	De-risked technology solution ready for commercialization

GCMI Offers:

- Early stage product strategy
- Design history file generation
- Client input and review
- Biomedical and mechanical engineering
- GMP compliant

- Preclinical testing
- Bioskills training
- Education
- GLP compliance
- AAALAC accredited

IMAT PI Meeting overview

- Respect confidentiality for presentation of unpublished data.
  - *This is not a public meeting and presentations do not represent a public disclosure*
- Note NCI program presentations throughout
- Group photo on Thursday PM break (~3:30pm)
- Welcome our guests!
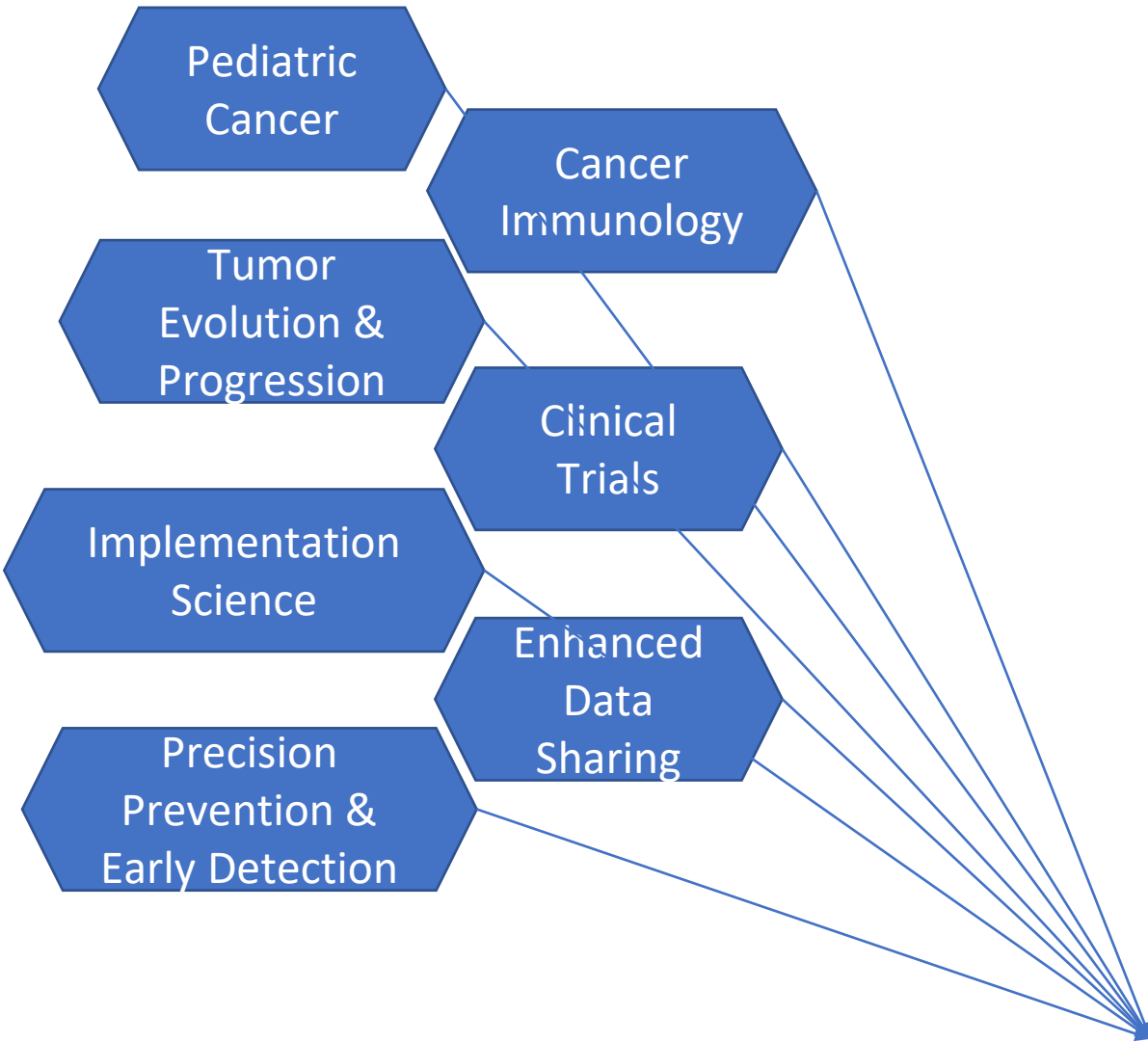- Logistics

2019 PI Meeting?

- **Accelerate progress** in cancer, including prevention & screening from cutting edge research to wider uptake of standard of care

- Encourage **greater cooperation and collaboration** within and between academia, government, and private sector

- Enhance **data sharing**

Blue Ribbon Panel

Blue hexagons (left):
- Pediatric Cancer
- Cancer Immunology
- Tumor Evolution & Progression
- Clinical Trials
- Implementation Science
- Enhanced Data Sharing
- Precision Prevention & Early Detection

Green boxes (right):
- Intensify Research on Drivers of Childhood Cancers
- Immunotherapy Translational Science Network
- 4D Human Tumor Atlases
- Overcome Cancer's Resistance to Therapy
- Retrospective Analysis of Patient Specimens
- Minimize Debilitating Side Effects
- Network for Direct Patient Engagement
- National Cancer Data Ecosystem
- Expand Cancer Prevention and Early Detection Strategies
- Develop New Cancer Technologies

Blue Ribbon Panel

Recommendations

Pediatric Cancer

Cancer Immunology

Tumor Evolution & Progression

Clinical Trials

Implementation Science

Enhanced Data Sharing

Precision Prevention & Early Detection

- Intensify Research on Drivers of Childhood Cancers
- Immunotherapy Translational Science Network
- 4D Human Tumor Atlases
- Overcome Cancer's Resistance to Therapy
- Retrospective Analysis of Patient Specimens
- Minimize Debilitating Side Effects
- Network for Direct Patient Engagement
- National Cancer Data Ecosystem
- Expand Cancer Prevention and Early Detection Strategies
- Develop New Cancer Technologies

Blue Ribbon Panel Recommendations and Cancer Moonshot Implementation Teams

- Network for Direct Patient Engagement
- Cancer Immunotherapy Network
  - *Pediatric Immunotherapy*
  - *Adult Immunotherapy*
- Overcome Drug Resistance
- National Data Cancer Ecosystem
- Drivers of Childhood Cancers
- Symptom Management
- Prevention and Early Detection
  - *High Risk Cancers*
  - *Prevention & Screening*
- Human Tumor Atlases
- Retrospective Analysis of Biospecimens
- New Enabling Cancer Technologies

NCI Support for Technology Development
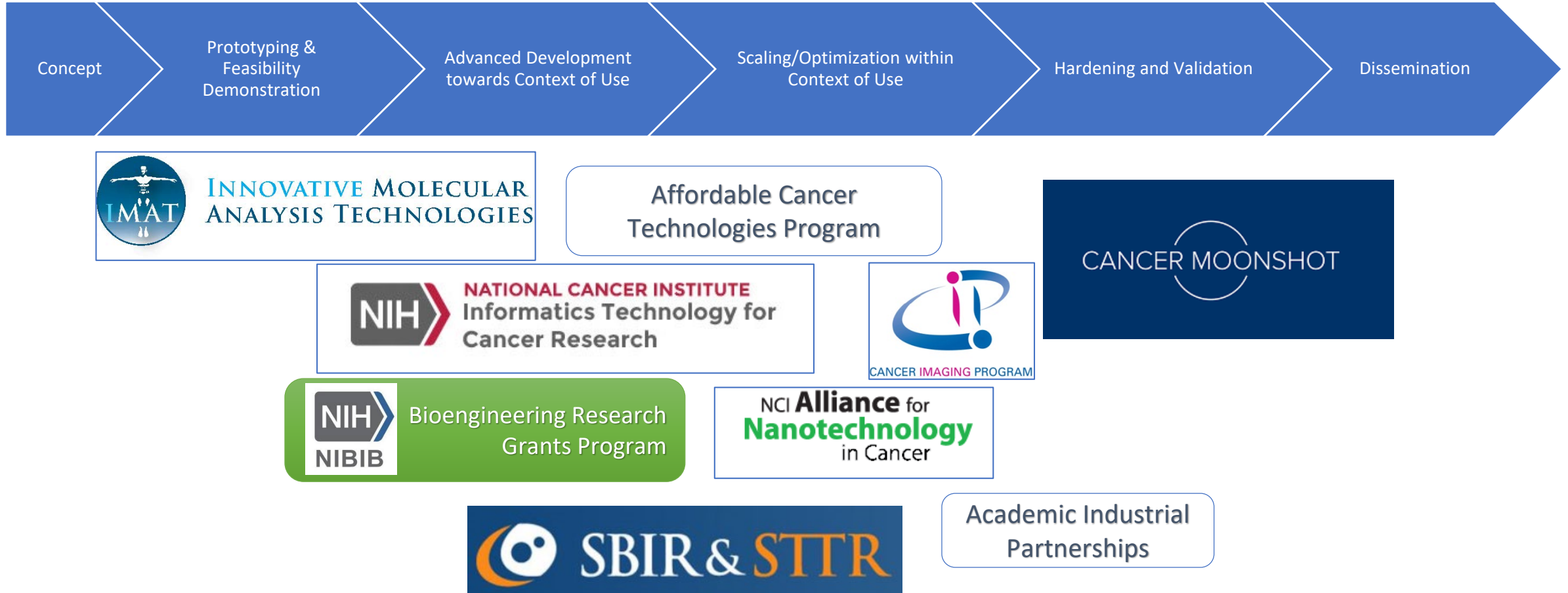
Mission:

To cut assay development times in half *through the creation of an open database for liquid biopsies, accelerating the development of safe and effective blood profiling diagnostic technologies for patient benefit.*

www.bloodpac.org

BloodPAC Members

Minimal Technical Data Elements – Variables that are required for submission of samples to the BloodPAC Data Commons.

Pre-Analytics
- Analyte
- Sample Collection
- Patient Factors

Analytics
- Sample Storage and Processing
- Assay SOP

Clinical Validation
- Assay Results
- Patient Data
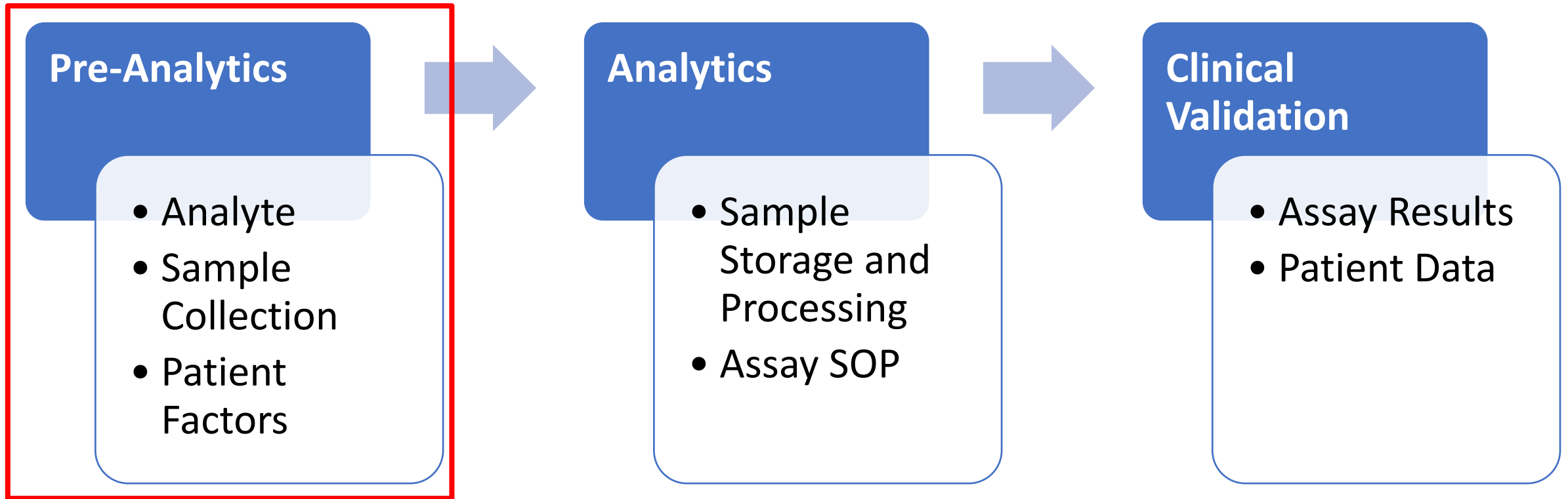
Pre-Analytical MTDEs: <u>variables</u> that would affect **assay performance,** and are required for submission of samples to the Data Commons.

FDA has already agreed to the following pre-analytic cfDNA MTDEs

cfDNA MTDEs
Blood collection tube type
Blood fractionation approach
Time to fractionation
Time to freezer
Storage temperature
Shipment temperature
DNA isolation method name
DNA quantification method
DNA yield
Sample type
Time to assay