

Joint Immuno-Oncology & Core Protocol Team Meeting



# Joint IO/Core Protocol Teams Meeting Participants

Name	Organization	
Gigi Hirsch	NEWDIGS	Joint IO/Core Protocol Team Lead & Meeting Facilitator
Azrina Azhar	NEWDIGS	Scribe
Elizabeth Apgar	NEWDIGS	
Stella Blackburn	IQVIA	
Kay Larholt	NEWDIGS	
Jacqueline Law	Flatiron Health	
Irene Nunes	Flatiron Health	
Megan O'Brien	Merck	
Victoria Paly	Takeda	
Ken Quinto	FDA	
Priscilla Velentgas	Merck	



# Agenda for Joint Team Meeting

- Brief review of case study & key questions
- Revisit Core Protocol (see draft outline)
  - Purpose, target deliverables, inter-dependencies, roadmap
- Define next steps and priorities for Joint Team



# Case Study #1: Key Questions

#### **Case Study**

**Disease:** Non-Small Cell Lung Cancer (NSCLC)

**Product Class:** Immune Checkpoint Inhibitors (ICIs)

Clinical Outcome/Impact

**RWE Production Process** 

Case-Specific

#### **Question #1:**

Can we improve our ability to predict which patients with advanced NSCLC will benefit from ICIs?

Generalizable

#### **Question #2:**

Can we develop the models in ways that reduce the likelihood of bias that could perpetuate or exacerbate health disparities?

<u>Health Disparity</u>: A type of **preventable health difference** that is closely linked with social, political, economic, and environmental disadvantage.





## Core Protocol: Key Discussion Points

## 1) Define purpose of a Core Protocol for a Predictive Outcomes Platform

 Advance from one-and-done predictive modeling studies to a scalable, distributed platform.

### 2) Define target deliverables from this team

- Communication: Concept overview? Framework? Call-to-action?
- Core Protocol
  - Template
  - Case-specific (NSCLC/ICI case, Federated Machine Learning)



# Core Protocol: Key Discussion Points (con't)

## 3) Identify critical inter-dependencies with other teams

- Immuno-Oncology
- Methods
- METRICS
- Precision Reimbursement

## 4) Develop high level project plan for 2023

- For June Design Lab
- For November Design



## Proposed Workstreams to Consider

- 1. Communication (research brief/publication)
- Core Protocol for a Predictive Outcomes Platform concept proposal?, call to action?

#### 2. Develop a Core Protocol

- Generalizable framework/template & guiding principles?
- Populate it for our first case study?
  - NSCLC & ICIs
  - Federated Learning



## Joint IO/Core Protocol Team Plan

November 2022-June 2023

#### Role & priorities

- Core Protocol Team
- Immuno-Oncology Team

Critical Inter-dependencies

Target goals/deliverables for June Design Lab

Workstreams & sub-teams?