

## **FoCUS Project | NEWDIGS**

*Current Remits Effective Until April 2023,  
Subject to Review after Respective Team Calls*

### **WORKSTREAM SEEKING MEMBERS**

#### **Precision Reimbursement Adoption Monitoring (PRAM) Project**

Team Lead: Mark Trusheim

The team and database aim to increase transparency of value-based contracts in the market place. However, creating a new database is not easily feasible, so the team plans to contribute a research paper that will identify the value propositions and incentives of engaging in such an activity. By doing so, they hope to facilitate the creation of similar databases in the future, promoting transparency and better outcomes for all stakeholders involved in value-based contracts.

#### **Exploring the Possibilities of Risk Pools for Chronic Therapies in Rare Diseases**

Team Leads: Lisa Feng, Michelle Harika, Mukesh Sharma

#### **September 2023 Design Lab Case study: Part 3**

The October 2022 and April 2023 Design Labs fostered great momentum around exploring Precision Financing solutions in chronic rare disease. This team will be working with the Precision Reimbursement Team and other interested parties on a follow up case study in September 2023.

#### **Analyze the Interactions of 340B and ASP with Value-Based Purchasing Arrangements**

Team Lead: Mark Trusheim

The Federal 340B drug pricing program required discounts may disincentivize the use of Value-Based Purchasing arrangements (VBPs). The use of ASP-based “Buy & Bill” reimbursement may also inhibit VBP use. This team examines the interactions of these programs, describe scenarios (perhaps quantitatively) when these programs do and do not interfere with VBPs, and suggest possible reforms when they do. The team is fully dedicated to producing a comprehensive and influential white paper.

#### **Policy Tea**

**PDUFA VII Implications**

Team Lead: John Glasspool

Our interest in The Prescription Drug User Fee Act (PDUFAVII) lies in the section, *'Ensuring the effectiveness of the human drug review program': Enhancing regulatory science and expediting drug development*. The first half of 2023 investigated designing a pilot proposal for the FDA to include Precision Financing with effectiveness and post approval study requirements.

**Pipeline Analysis and Modeling (PAM) Predictions and Understanding the Systems' Capacity for Cell and Gene Therapies**

Team Leader: Mark Trusheim, Claire White, Colin Young

In partnership with healthcare providers and systems, Team will assess the current and future practices related to the infrastructure and administration of cell and gene therapies in both in- and out-patient settings. Aims to identify feasible and acceptable solutions to overcome barriers that impact patient access, such as provider availability, hospital capacity, and availability of necessary products. The goal is to highlight best practices, challenges, and issues that affect providers' capability and engage patients in a multi-stakeholder setting to suggest patient-centered solutions.

**Paying For Cures Toolkit: Navigation and Design**

Team Leader: Karen Geary

This team is responsible for maintaining the Toolkit website with industry updates and all relevant briefs and progress notes from FoCUS. With the move to Tufts Medical Center, we are using this opportunity to enhance the user experience, making improvements to the navigation and design. Other Toolkit activities will include the development of visual presentations of information as downloadable infographics and/or slides.