Data Visualization Tool to Map CDER's Priorities and Deliverables: *Role of Public-Private Partnerships*

Rama Rayavarapu[1], Md. Rashedul Hasan[1], Mitra Ahadpour[1], ShaAvhrée Buckman-Garner[1], Ameeta Parekh[1]

[1]FDA/CDER/Office of Translational Sciences

Background: One of the primary charges of the Food and Drug Administration (FDA) is to advance public health by streamlining drug development. To support this mission, the FDA's Center for Drug Evaluation and Research (CDER) advances safe and effective drug products to the market through its regulatory review process, and stimulates innovation in drug development. The process ranges from scientific reviews of drug product applications, to collaborations with internal and external stakeholders on regulatory science and innovative research to address areas of unmet needs. These activities are guided by key directives such as the 21st Century Cures Act[1] and the User Fee Acts[2].

Recognizing a need to further accelerate the translation of laboratory discoveries to the patient, the FDA published a landmark report in which the Critical Path Initiative (CPI) was established[3]. The CPI calls for an increase in collaboration between biomedical industry stakeholders to accelerate the rate at which innovative therapies are delivered to the public. A Public-Private Partnership (PPP) is a collaborative group involving multiple stakeholder organizations including at least one non-profit organization (e.g. government or foundation) and at least one for-profit organization (e.g. pharmaceutical company). To accomplish its mission and key directives, CDER collaborates with several PPPs and guides regulatory research. CDER Staff and offices address and track ongoing internal activities, as well as the deliverables through their PPP collaborations. A consolidated database with a linked interactive tool to visualize the cross-Office activities would provide a one-stop-shop to visualize activities, assess gaps, and determine redundancies within CDER and assess the impact of PPP activities on CDER's mission.

Objective: The goal of this project is to create an interactive tool linked to a dynamic database that can be updated as needed, that visualizes organizational activities. This tool can be used to map CDER wide activities

Methods: We identified key priorities from 21st Century Cures Act[1], Prescription Drug User Fee Act VI[2], 2011 Advancing Regulatory Science at the FDA[4], Critical Path Initiative[3] and CDER RGC Research Goals and Objectives. Additionally, we created a database using publicly available information from the PPPs associated with CDER. There are currently 43 CDER associated PPPs (August 2019). This project uses a tool developed from the D3.JS (Data-Driven Document Java Script) visualization library to identify the activities and deliverables of the PPPs associated with CDER, and assesses how they map to FDA's and CDER's public health mission and congressional mandates. The aggregated PPP data are stored in a queryable PostgreSQL database and visualized via an interactive dashboard that can be accessed from any web browser.

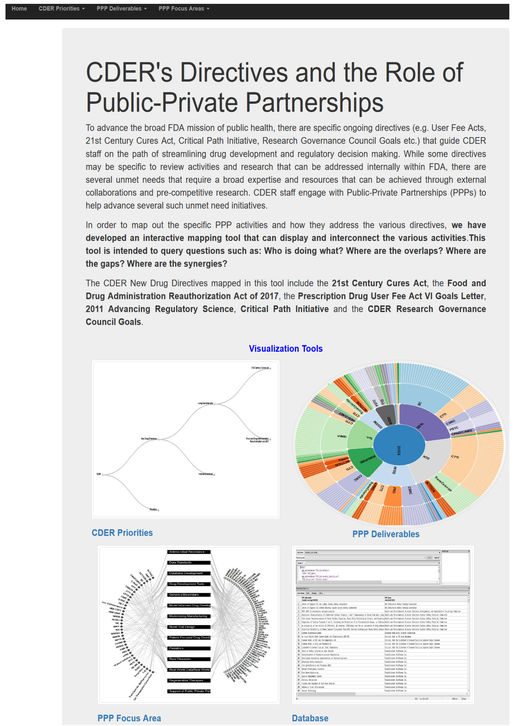

Figure 1. **Dashboard for Data Visualization Tools.** A fully interactive dashboard was developed to house and display the tools generated to analyze data related to CDER PPP priorities and deliverables.

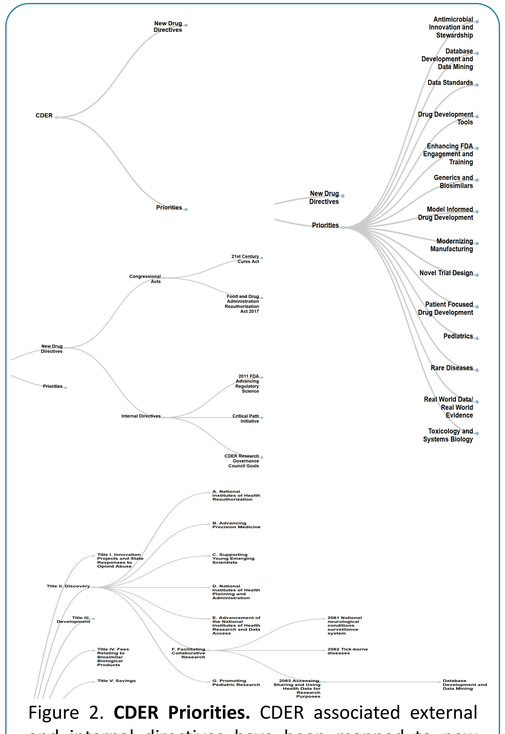

Figure 2. **CDER Priorities.** CDER associated external and internal directives have been mapped to new drug priorities using a tree diagram. The tool guides users to priorities via directives and vice versa. Additionally, a search function has been added to further make directives easier to assess.

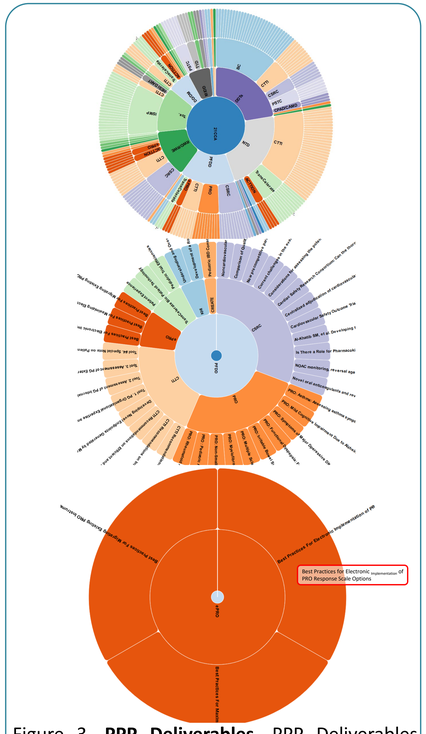

Figure 3. **PPP Deliverables.** PPP Deliverables have been mapped to directive specific priorities. The size of each wedge represents the contribution of each PPP to the priorities displayed.

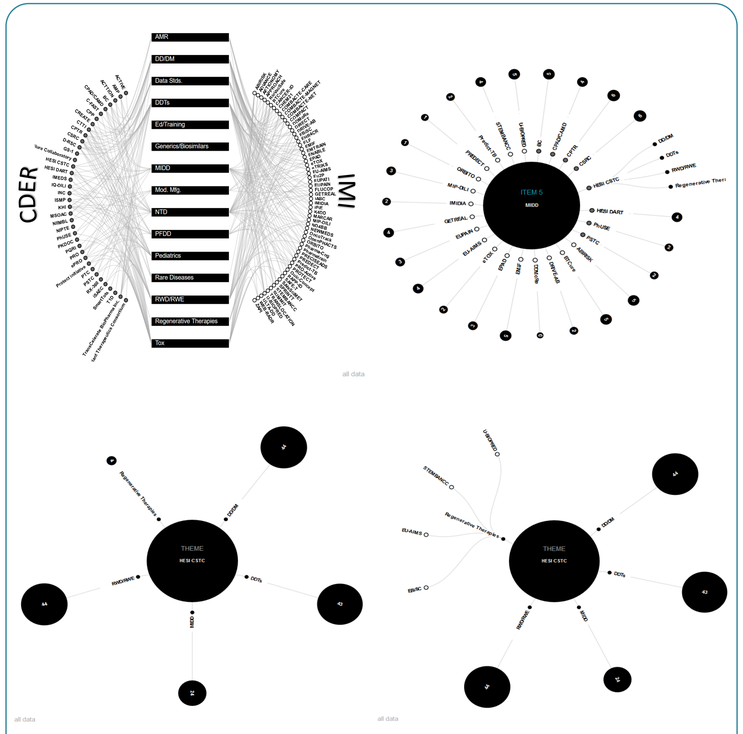

Figure 4. **PPP Focus Areas.** PPPs have been mapped by priority and therapeutic area or population. The tool displays PPP relationships with each focus area as well as the relationship between various partnerships in order to perform overlap and gap analysis.

Results: Figure 1 depicts the dashboard developed to display the data visualization tools generated from the PPP Deliverables Database. Figure 2 displays a tree diagram developed to track the key provisions from major CDER directives. Figure 3 depicts a sunburst diagram that shows the relationship between CDER PPP deliverables and various directive specific priorities. The tool shows both the relationship and impact of PPP deliverables on directive specific priorities. Figure 4 shows the relationship between various focus areas and PPPs. The tool can be utilized to identify overlaps and gaps in PPP activities and focus areas.

Future Directions: Currently, the tool has been applied to map the deliverables and activities of CDER associated PPPs, and will be expanded to include the activities and deliverables from the PPPs established by the European Innovative Medicines Initiative (IMI). The tool has been built with the broader goal of developing an automated platform for data visualization that can display organizational activities and their progress towards addressing specific public health needs.

References

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