# Processes & Publications

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# Background

- What will the registry contain? …e.g. non proprietary data
- Who will contribute to it?
- Who will benefit?...public, FDA, stakeholders
- The value if the registry is in its output…see #1
- One of the “rules of engagement” with FDA is public access to data and publications…even if jointly developed through partnerships
- The processes are governed by applicable federal laws and regulations related to intellectual property, anti-trust, and guidance development

# How it should work: FDA view

- Data access should be available to all, however, certain restrictions may be placed to protect existing commercial interests
- Publications resulting from the registry should be attributed based upon original contributions to outcomes and the manuscript/s
- If FDA is a co-author, the publication needs to be based solely assessment/discussion of scientific outcomes, and should not be interpreted as official Guidance

# How Will Registry Be Used?

- Partners, including FDA, contributing to the design and development of the registry will have access to the data therein
- At an appropriate time, these data will be made available to the public
- The registry may provide a way to close the Total Product Life Cycle loop and feed back to inform new premarket activities
- FDA may use registry data to inform future Guidance development

# Considerations

- A governance board should be established that includes representation from all stakeholders
- FDA's participation will be as a federal liaison, with no fiduciary role
- The activities taking place should be harmonized with goals and mission of the registry effort, as defined by the stakeholders