

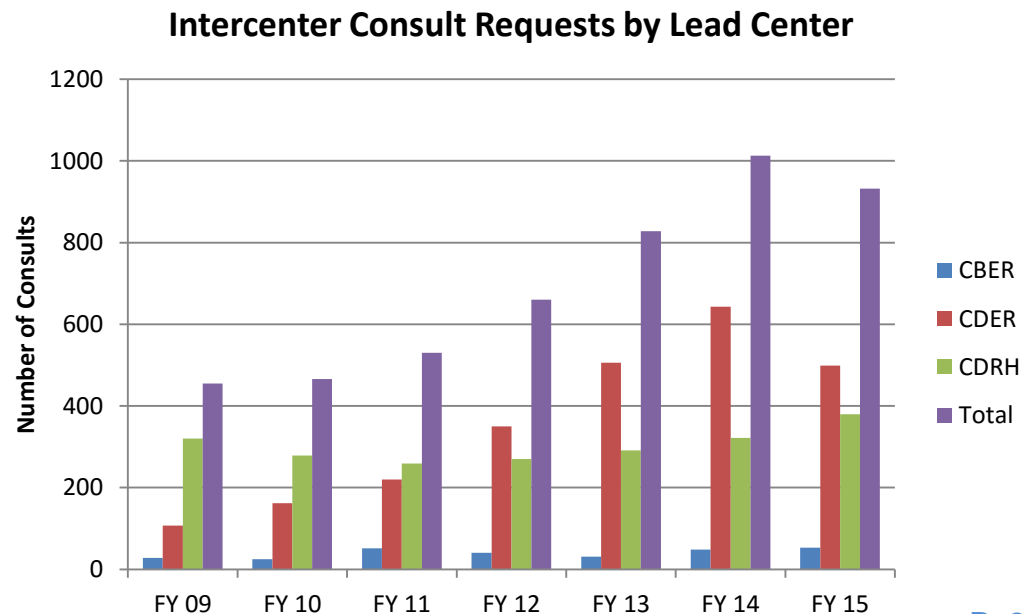
Improving the Intercenter Consult Process

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Topics

- Challenges identified in the combination products review process
- “Mapping” existing process and future state
- Improvements and progress





Challenges in the combination product consult process

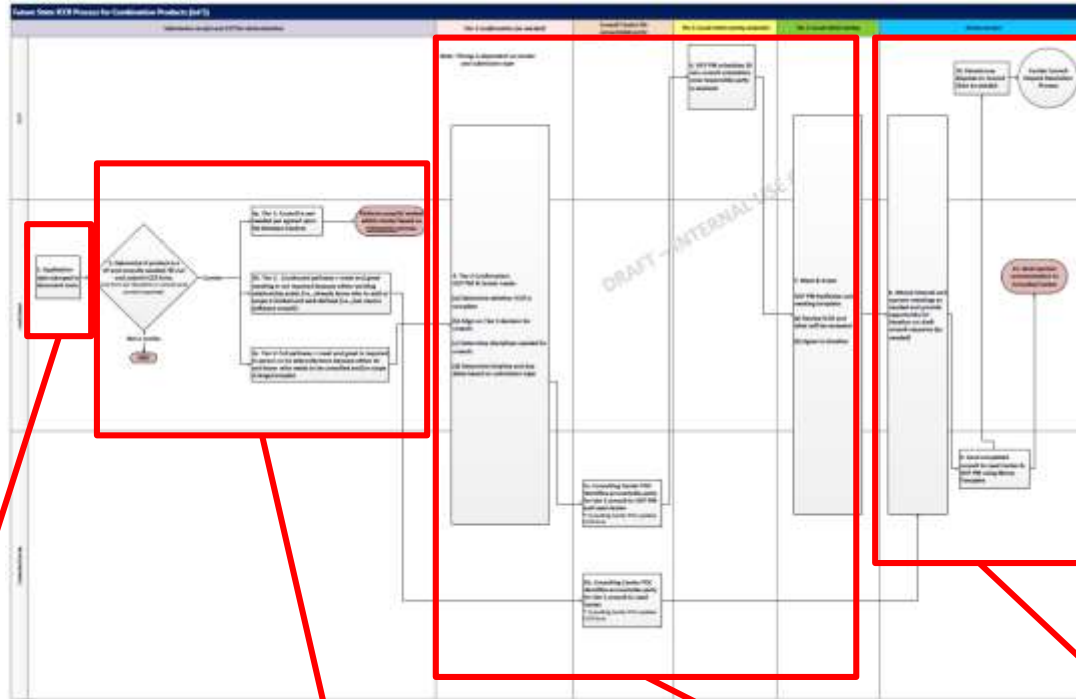
- October 2015 – Report on Intercenter Consult Process
- Identified several issues with existing process:
 - Differences in review timelines, review policies/practices, and application types
 - Separate tracking systems
 - Unclear communication channels between centers



Evaluating the Intercenter Consult Request (ICCR) Process

- March 2016 – Launch lean management mapping for ICCR process
 1. Capabilities Assessment
 2. Current-State ICCR Process
 3. Future-State ICCR Process
- Combination product council mission includes to “Modernize the inter-center consultation process ...”

Overview of New ICCR Pilot Process



Submission receipt

Combo Product identification and consult categorization

Consult assignment

Review closeout

Key Improvements

Tiered System

- Defines complexity
- Streamlines interactions
- Ensures appropriate internal stakeholder involved

Approach to Implementing Improvements

- Implement improvements without unnecessary disruption to existing best practices
- Outreach and training to staff on combination products and consult process improvements
- Centralized process resources for staff
- Pilot first in offices and divisions that represent a variety of submission and product types
 - Monitor through data analysis, audits, and direct staff feedback
 - Allow flexibility to adapt process based on feedback

How Process Improvements Help Address Identified Issues/Challenges

- To address different review timelines/review practices:
 - Defined target dates for identifying combination product submissions and engaging Consulted Center
 - Identified dedicated focal points in the Centers and the Office of Combination Products (OCP) to serve as resources for staff
 - Developed tiered process that leverages intracenter resources and appropriately engages intercenter resources

How Process Improvements Help Address Identified Issues/Challenges (cont)

- To address separate tracking systems:
 - Semi-automated consult form
 - Improved tracking of intercenter consults
 - Improved access time to each other's databases
- To address unclear communication channels:
 - More clearly defined roles -- who does what for consult process in both Lead and Consulted Center
 - Centralized list of consult contacts

Benefits of Consult Process Improvements

- Improved efficiency of intercenter collaboration
 - Engage necessary cross-Center expertise areas early
 - Improve understanding and alignment of intercenter review with overall submission review goals (PDUFA, MDUFA, etc.)
- Increased staff awareness of combination products and related review considerations

Status of ICCR Process Improvements

- Rolled out to initial Pilot groups in all Centers in August 2016
 - Phased roll-out will continue through mid-2017
- Periodic analysis of consult process data, focused audits, and staff feedback
- Real-time adjustments in response to identified issues
- Staff engagement and feedback has been positive

What can industry stakeholders do to help?

- Clearly identify when your submission is for a combination product
- Make sure that you submit your combination product to the correct Center
 - if you have questions about jurisdiction, contact OCP prior to submission
- Provide a “road map” in the submission to help staff navigate to relevant constituent part information
- Request representatives from the non-Lead Center and/or OCP for meetings when you feel is warranted
- Make sure that the feedback you received is from the Agency (i.e., the entire review team) and not just the Lead Center
- Provide feedback - Let us know what is and isn't working well



We're Here to Help!

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