What’s Next for Case for Quality?

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Setting the stage for today

In Progress

Commitment

Moving forward

Reimagining the system
Where are we today?

• Defined a third-party quality appraisal

• Initiated enrollment

• Performing appraisals

• Piloting metrics

• Piloting submission review modifications
Why a different assessment?
Why modify submission reviews?

• Leveraging trust
• Building capacity
• Enabling speed
• Enabling improvement
CDRH’s Commitment to Case for Quality

- CfQ will continue as a CDRH strategic priority
- Continue dedicated resources
- Driving change, fast wins
Moving forward
Case for Quality

Expand appraisal focus

- Incorporate maturity model design practice areas
- Enhance use and acceptance of design tools
- Identify submission and review modifications
- Pilot modifications to accelerate design improvements
Case for Quality

Product performance analytics

• Continue expanding collaborations

• Enable data access and standardization

• Establish data visualization methods

• Align with maturity model practice areas
Reimagining the system
Focus on organizational performance

- Continue to develop metrics and key performance indicators
- Establish common performance visualizations
- Move from static snapshot and inspection to continuous perspective
- Appraisal to learn capability and drive improvement
Accelerating and enabling patient access
Continuous learning system

- Monitor and respond to real world evidence
- Identify organizational excellence practices, behaviors, and metrics
- Adapt regulatory process, submissions, and requirements