

# MDIC Case for Quality: CAPA Process Improvement

#makeCAPAcool Project

## CASE FOR QUALITY CAPA WORKSTREAM

### FDA, MDIC & Industry Members

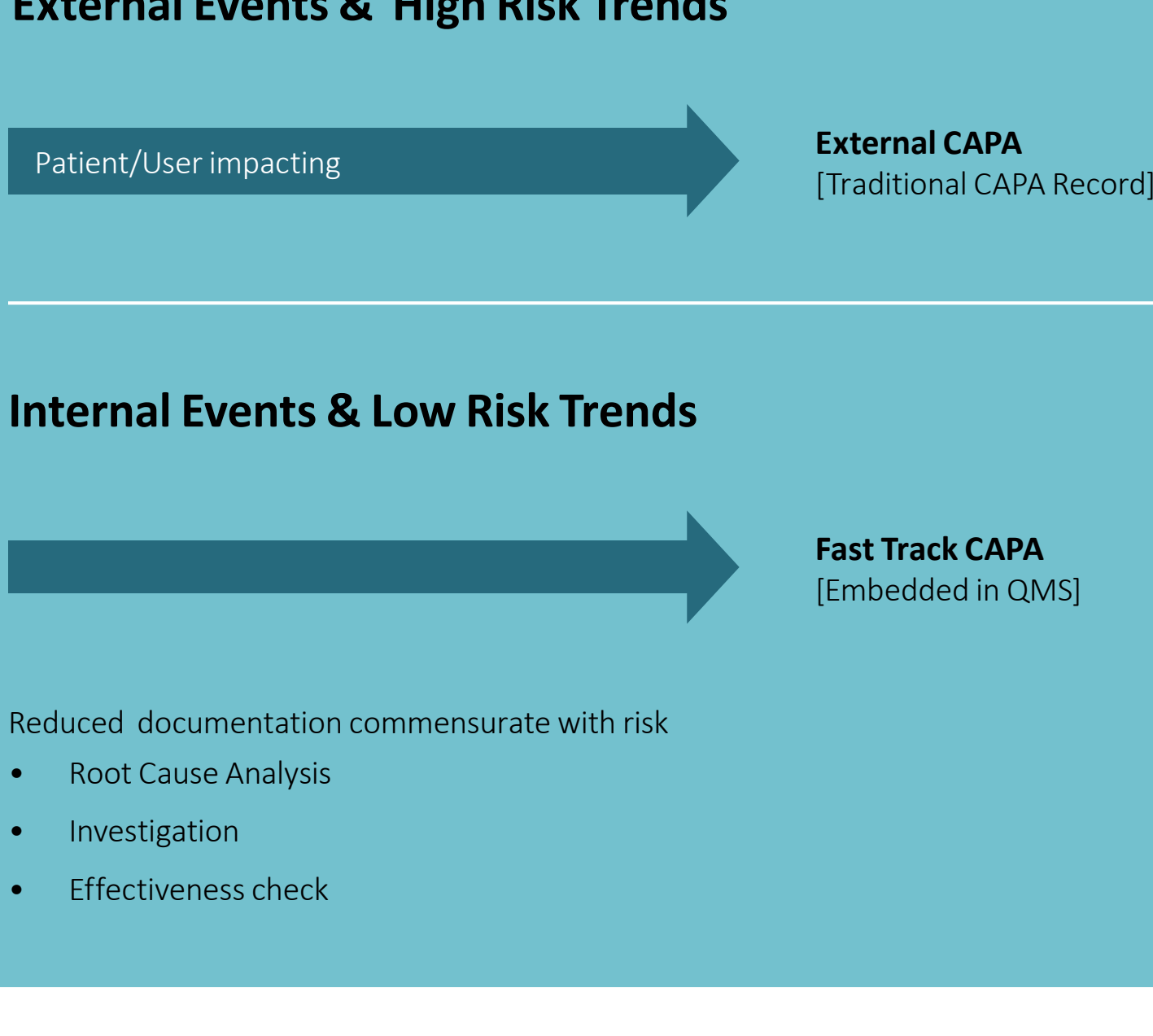


## What is Changing?

From	To
<ul style="list-style-type: none"> <li>Compliance requirement</li> <li>“One size fits all”</li> <li>“A punishment”</li> <li>Documentation focused</li> </ul>	<ul style="list-style-type: none"> <li>Solving problems to improve quality</li> <li>Risk-based/fit-for-purpose</li> <li>“A privilege”</li> <li>Impact-focused</li> </ul>

## What is the Proposed Framework?

Proposed CAPA Framework: Two Main Flows



## What are the Benefits?

- More issues addressed**
  - Faster**
  - Less burden/cost**
  - Engaged and excited employees**
  - Compliant**
- Safer better products faster!**

## Why should I sign up?

- Be the first one to take advantage of the benefits**
- Help shape the future of CAPA**

## How do I sign up?

**Contact your organization’s #makeCAPAcool team representative**  
If you do not yet have a representative, contact the Program leader (kathryn.merrill@medtronic.com)

**Provide written communication of your desire to pilot the process.**  
Communication should include how you meet the minimum enrolment requirements

- No OAI’s
- Good Standing with Regulatory bodies (obtained applicable certificates)