



**MEDTECH
MEETS
DIGITAL**

TAG 1 – SESSION F1

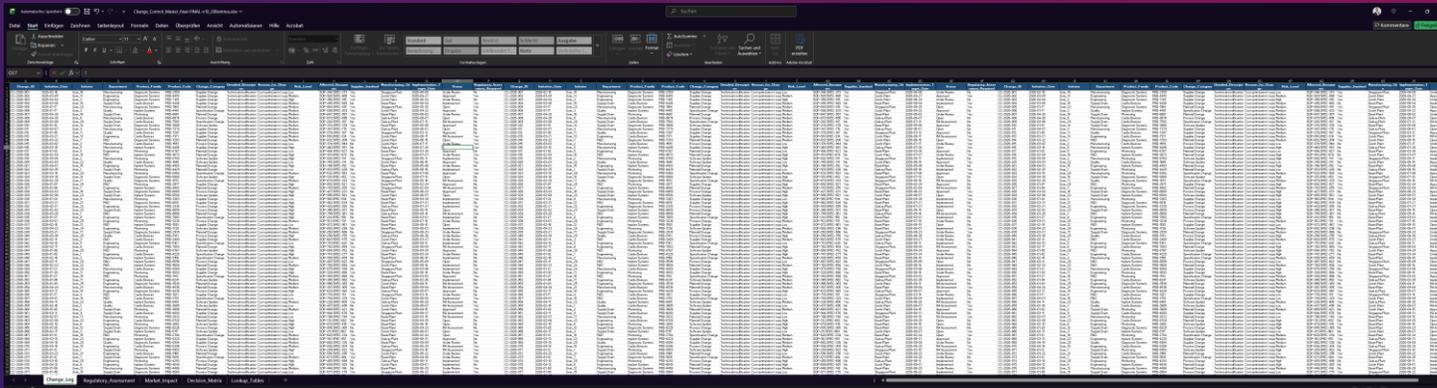
DIGITALE DURCHGÄNGIGKEIT:

ENTSPANNT DURCH PRODUKTÄNDERUNGEN & CHANGE NOTIFICATIONS

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ENTSPANNT DURCH PRODUKTÄNDERUNGEN & CHANGE NOTIFICATIONS

Änderungen im Unternehmen können den Zulassungsstatus beeinflussen. Insbesondere wenn sie als „significant change“ gelten. Ausgangspunkt ist oft die berüchtigte Datei *"Change_Control_Master_final-FINAL-v18 (2).xlsx"*, die regelmäßig für Panik sorgt.



The image shows a screenshot of an Excel spreadsheet. The spreadsheet is filled with many columns and rows of data, which appears to be a complex table or database. The columns are labeled with various identifiers, and the rows contain detailed information. The spreadsheet is displayed in a window titled "Change_Control_Master_final-FINAL-v18 (2).xlsx".

„Wir brauchen keine Software, wir machen das mit Excel“

Die Excel:



SPEAKERS

Tobias Busch

Product Manager
avasis Digital Platform
avasis AG



Thomas Winkler

Team Lead
Professional Service
avasis AG



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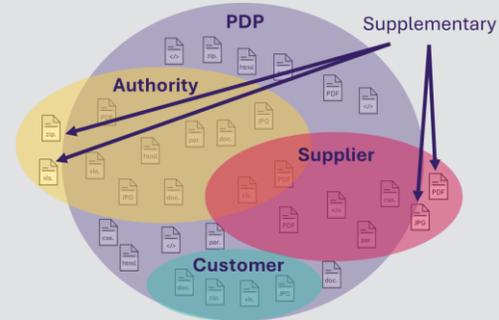
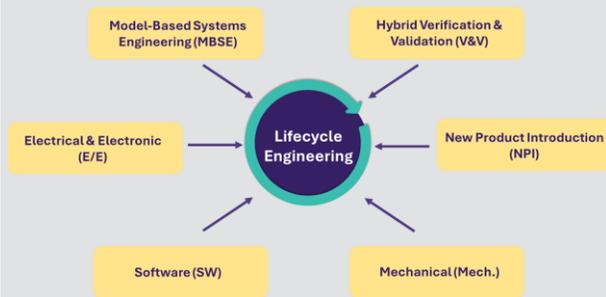


Wie läuft eigentlich ein significant change bei euch?

- 1 Wie erfahrt ihr im Unternehmen überhaupt von einer Änderung?
- 2 Wer entscheidet bei euch, ob eine Änderung ein „significant change“ ist?
- 3 Welche Tools nutzt ihr heute für Change Control und Impact Assessment?
- 4 Wo entsteht im Change-Control-Prozess aktuell der größte Aufwand oder Zeitverlust?
- 5 Wie sicher seid ihr, dass wirklich alle regulatorisch relevanten Änderungen erkannt werden?

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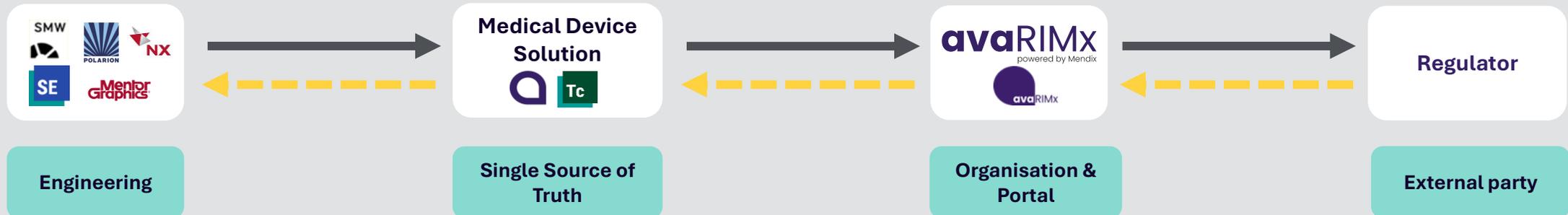


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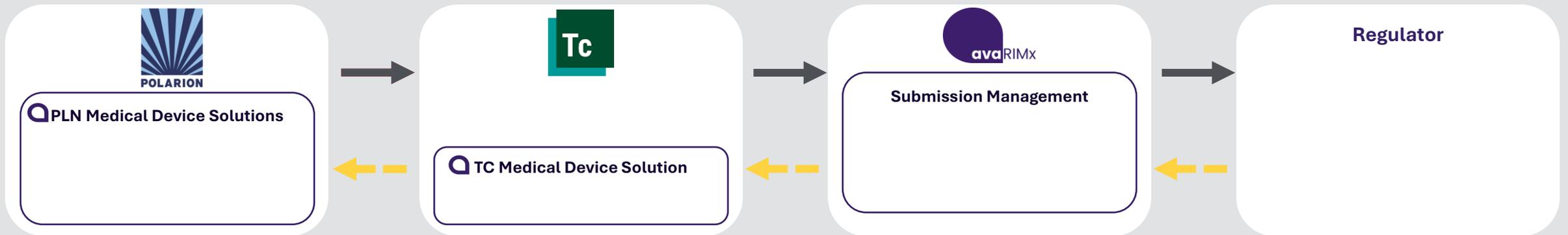
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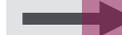
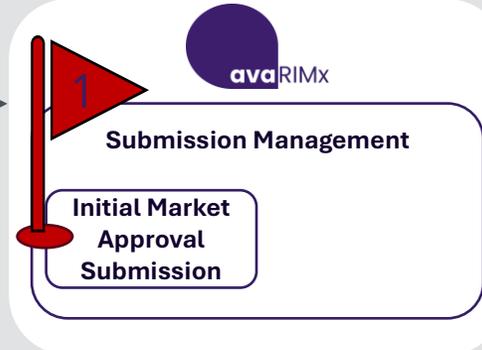
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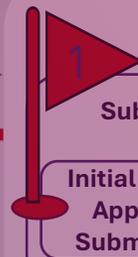
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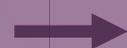
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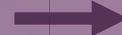
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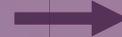
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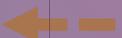
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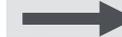
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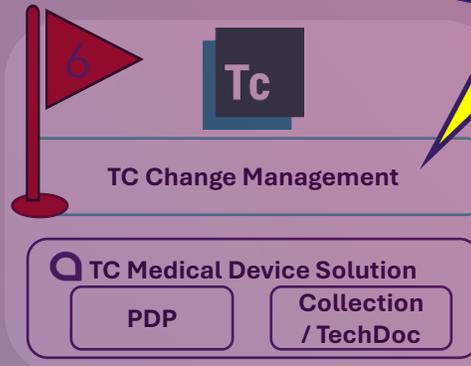
Software must be changed!

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TEAMCENTER CHANGE MANAGEMENT



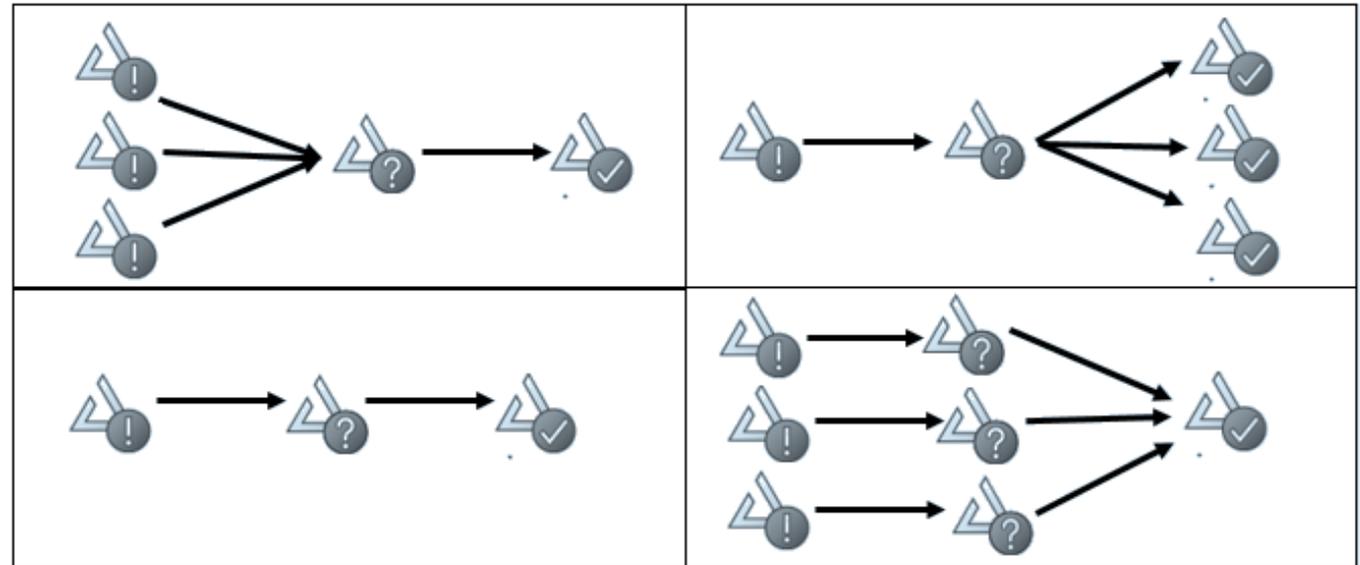
Problem Report documents a problem or issue



Change Request is a request to change or initiate an improvement

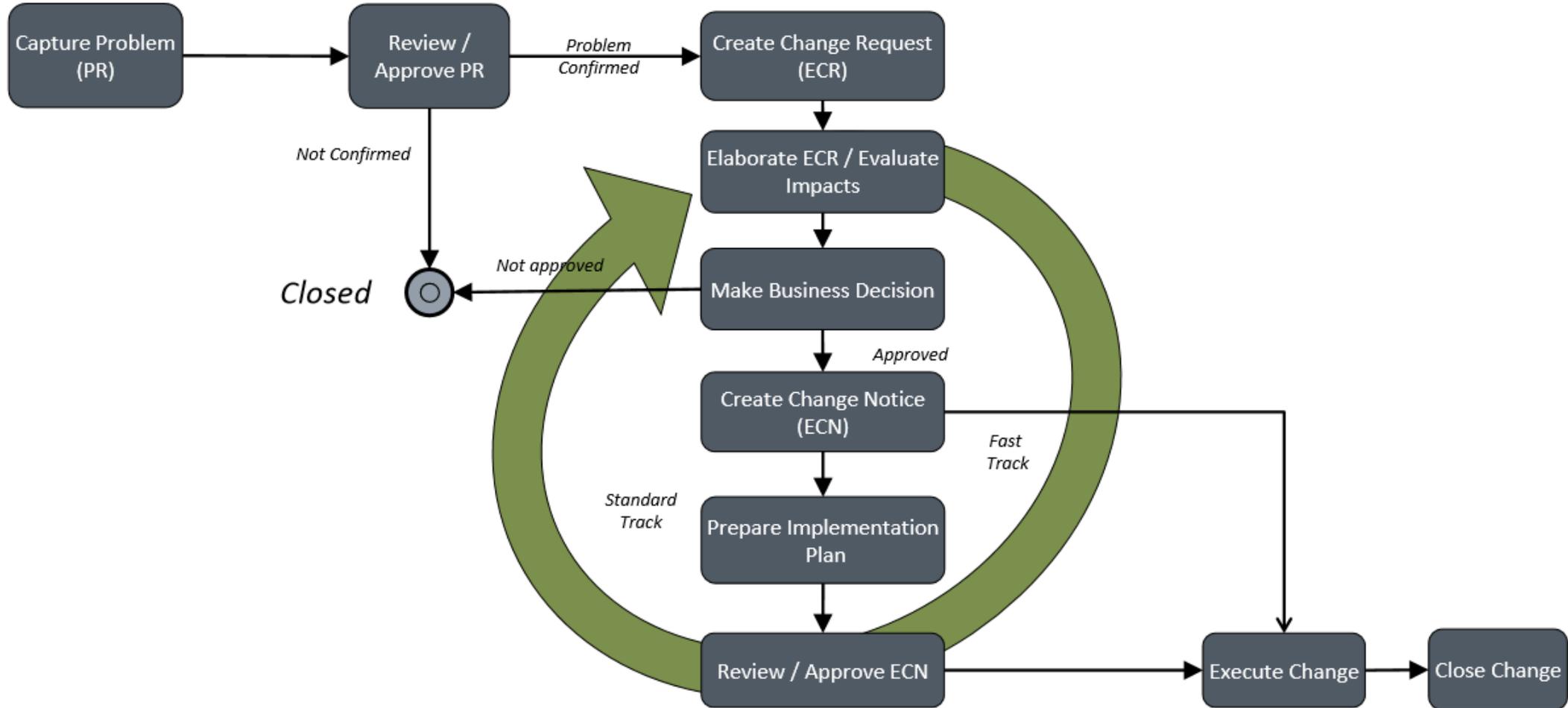


Change Notice authorizes and controls the implementation of approved ECRs



Evolution paths for change objects.
Arrows indicate implemented by relation.

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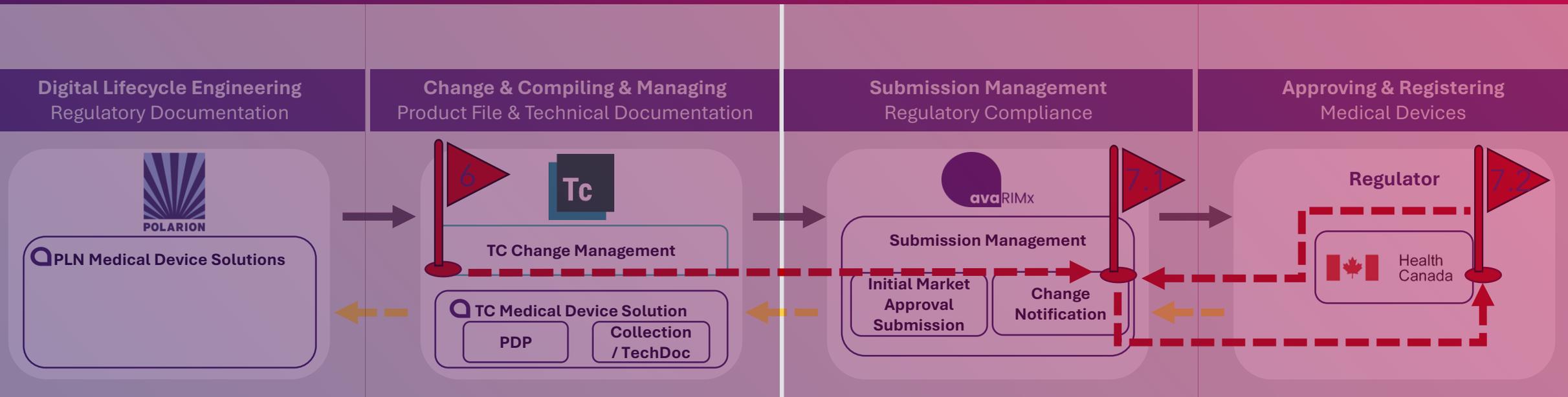
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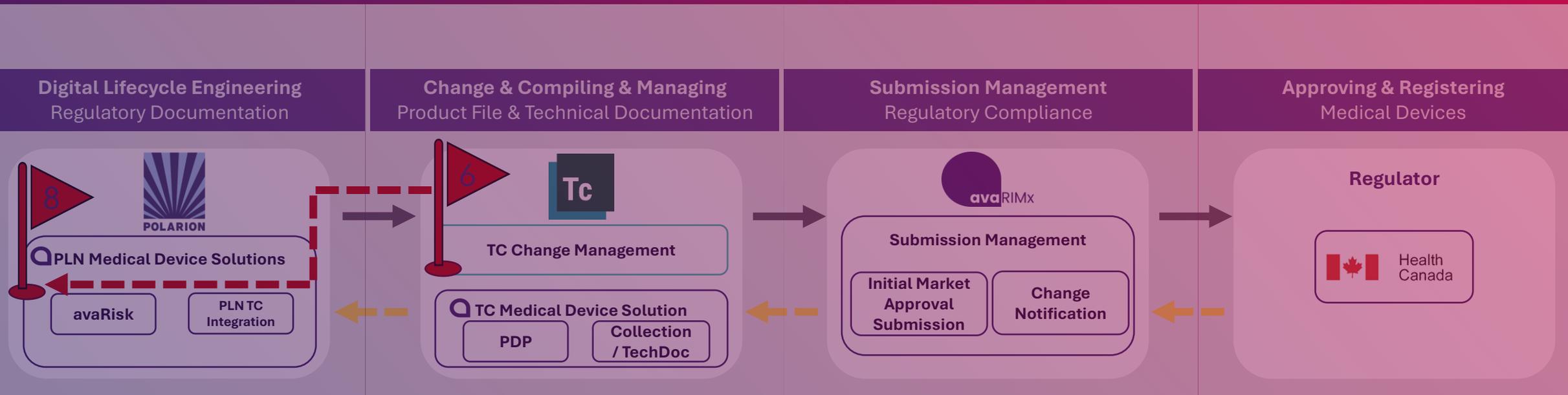
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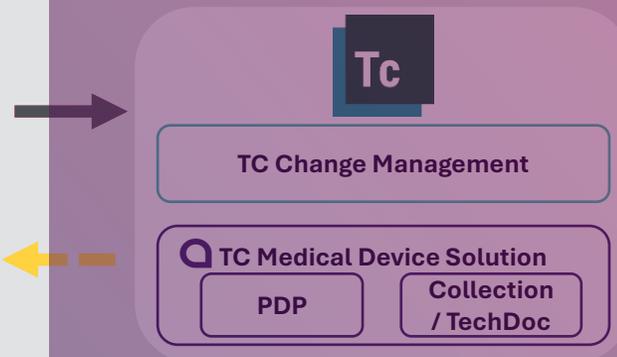


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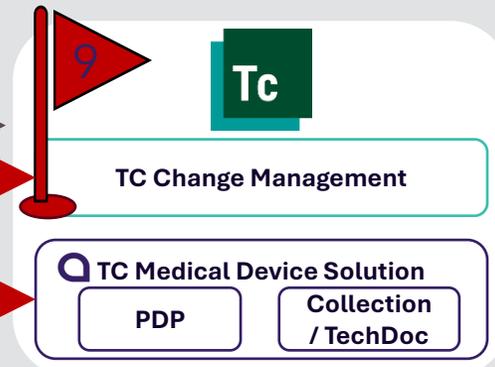
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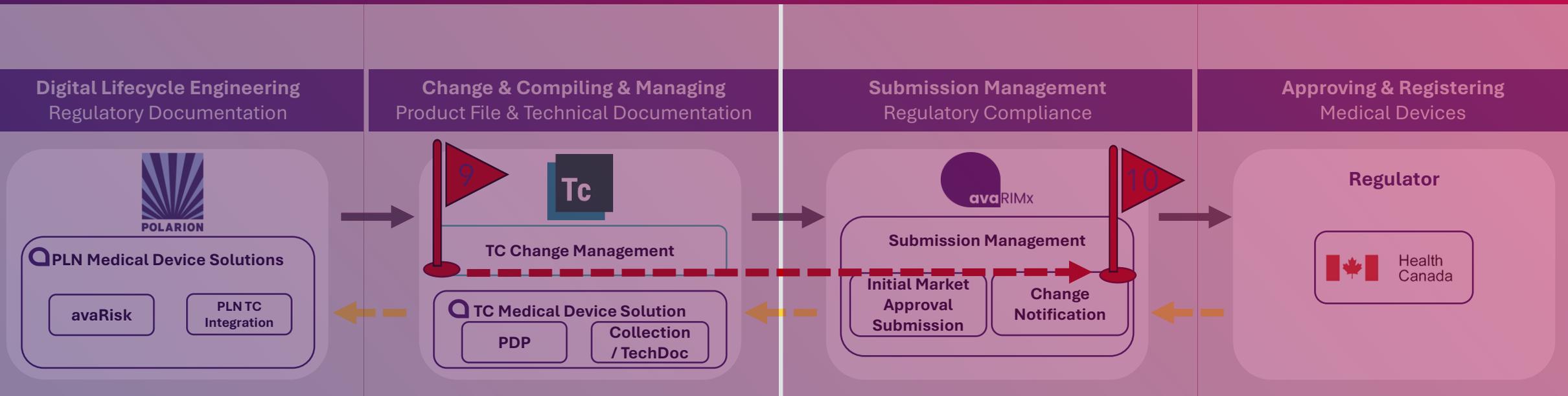
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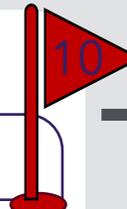
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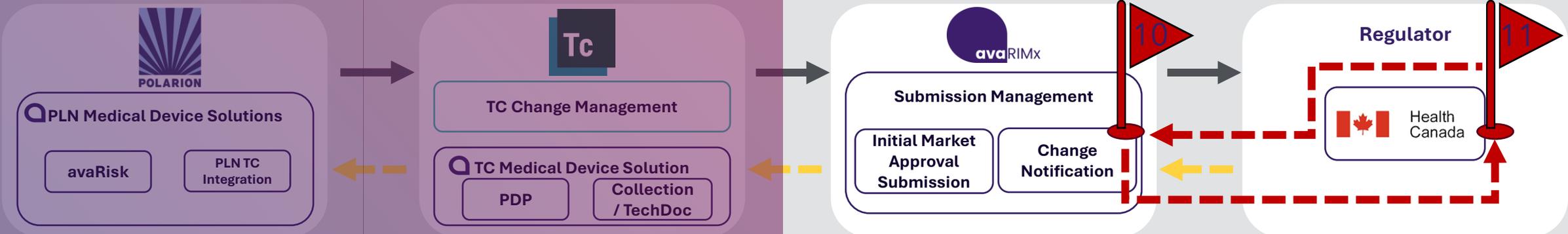


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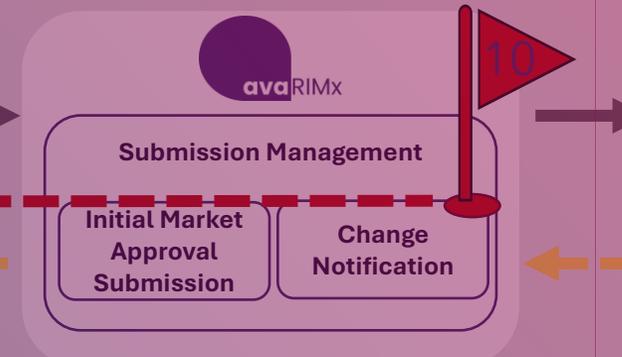
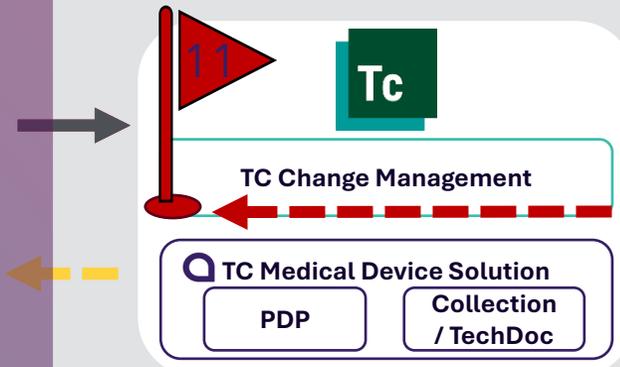
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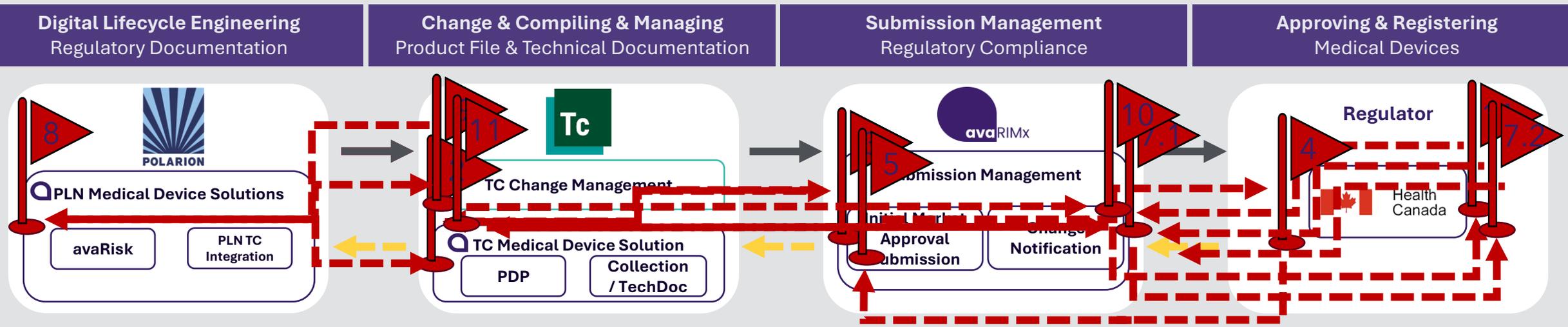
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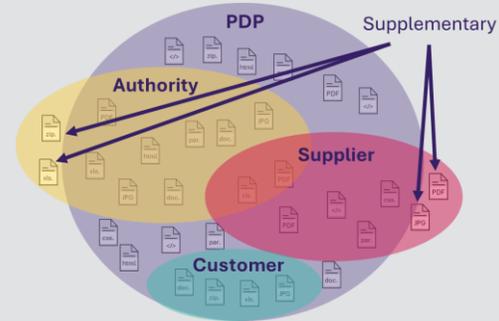
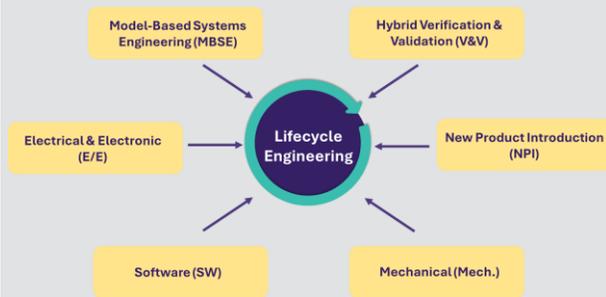


- 1 Was bräuchtet ihr konkret, um einen solchen digitalen Change-Control-Prozess bei euch umzusetzen?**
- 2 Welche Systeme spielen bei euch dabei die wichtigste Rolle und wo seht ihr Lücken?**
- 3 Wo seht ihr den größten konkreten Nutzen für euer Unternehmen?**
- 4 Was wären die größten Hürden bei der Einführung einer solchen Lösung bei euch?**
- 5 Womit würdet ihr morgen anfangen, wenn ihr nur einen Teil des Prozesses digitalisieren dürft?**

Die Lösung ist nicht nur Technologie sondern die richtige Kombination aus Prozess, Systemen und Zusammenarbeit.

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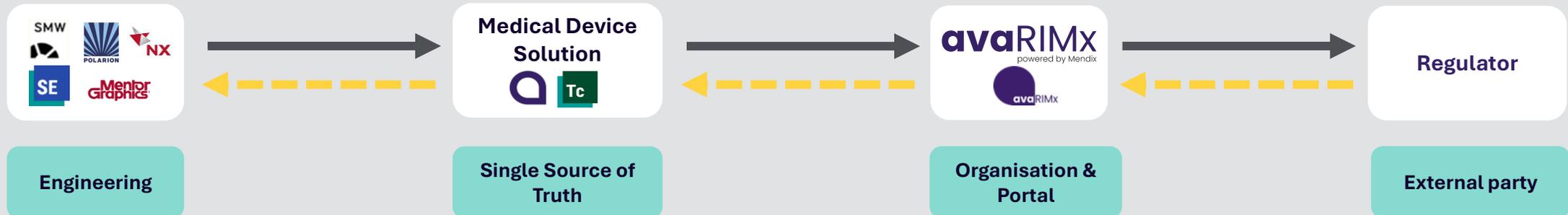


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Traceability – jede Entscheidung ist nachvollziehbar

Transparenz – jederzeit klarer Status aller Changes

Compliance – strukturierte, sichere Durchführung

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Take-away

Wenn wir diese Durchgängigkeit erreichen, kann Regulatory Affairs **entspannt und kontrolliert durch Produktänderungen und Change Notifications steuern!**
