



The Clinical Data
Science Conference

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Enhancing Protection of Confidential Commercial Information through Unified Cross-Functional Strategic Alignment

Integrated Data Analytics and Reporting
Clinical Data Standards & Transparency, Document Sharing

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Johnson&Johnson

Disclaimer:

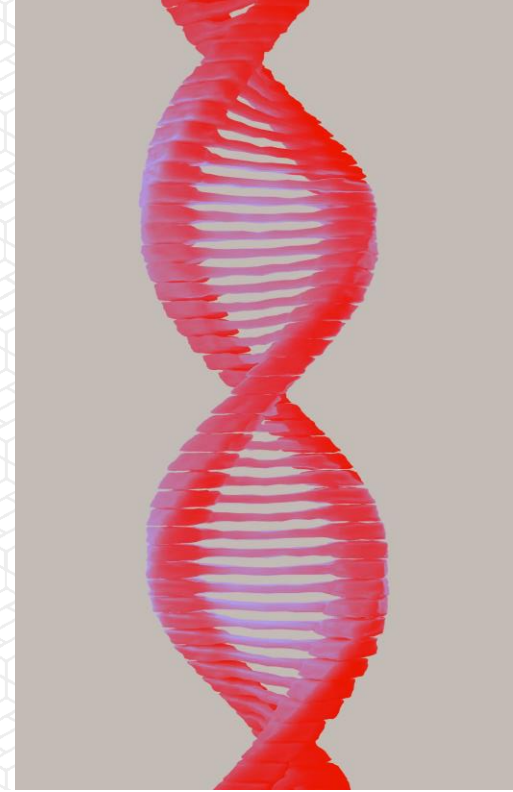
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Complexities of Confidential Commercial Information

Confidential Commercial Information (CCI): Undisclosed information that is proprietary in nature and if disclosed would concretely undermine the commercial or economic interests of the company.

Confidential Commercial Information is **Complex**:

- CCI is **unique** to individual programs
- CCI **varies** across developmental stages
- CCI is **continuously updated** based on disclosures & patent strategy



Disclosures by
the Numbers:
2025

3,056

Total Number of CCI Review Requests

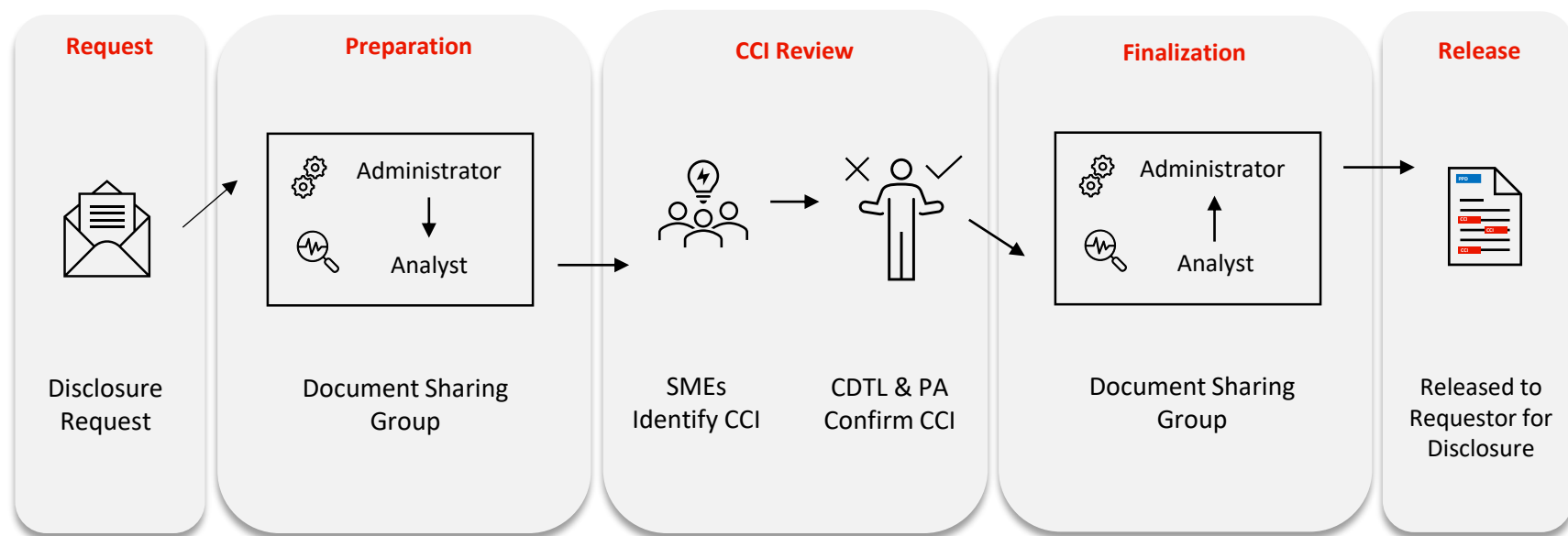
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Number of Therapeutic Areas Supported

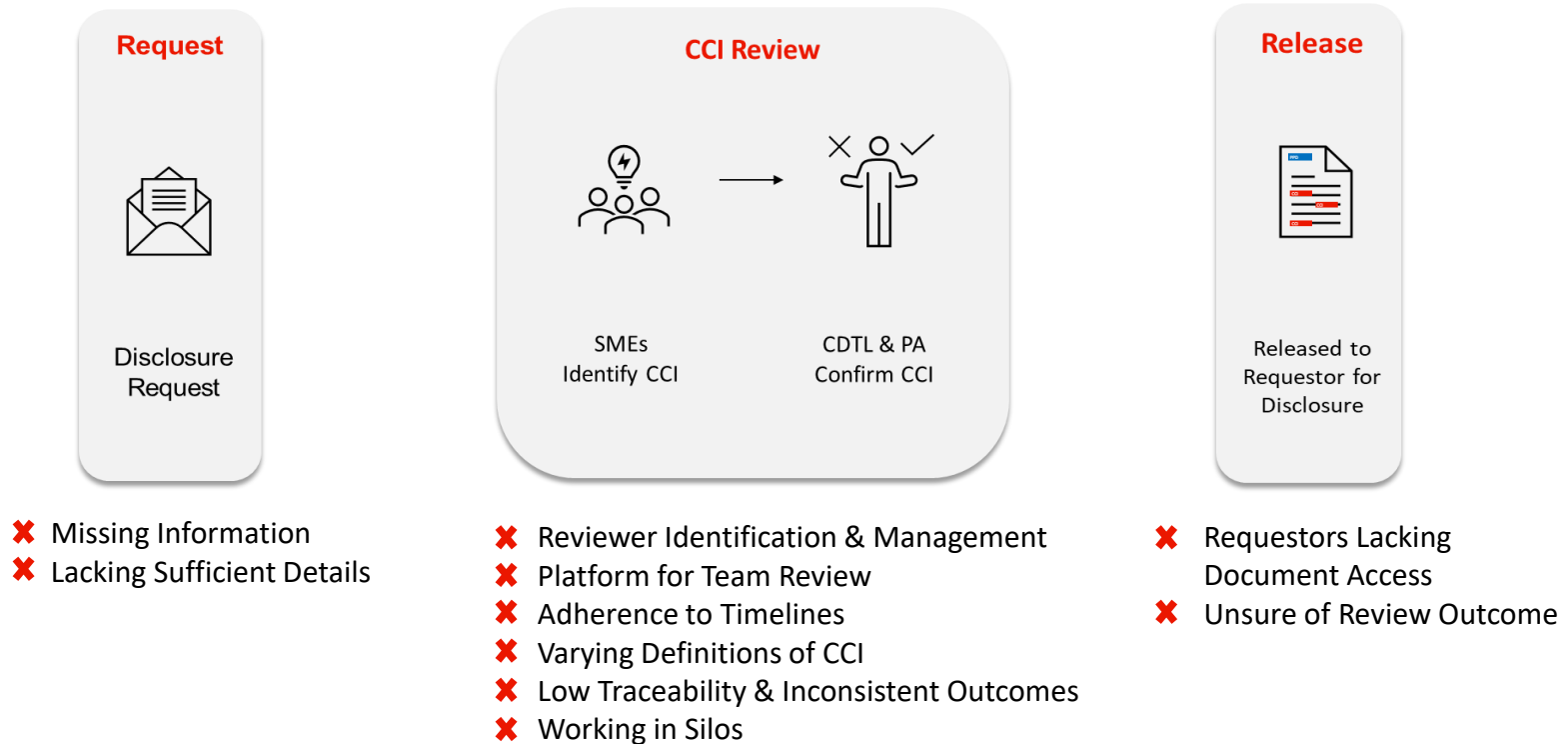
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Number of Internal Reviewers

Cross-Functional Review of Confidential Commercial Information: A Complex Process



Cross-Functional Review of Confidential Commercial Information: Many Hurdles to Overcome





Challenge: High Volume Reviews & Multiple Reviewers Increases CCI Disclosure Risk



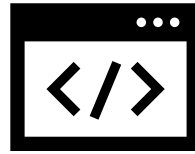
Solution: Standardization and Cross-Functional Alignment

Strategic Alignment Matters for Data Transparency



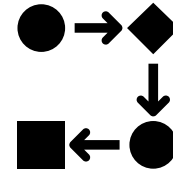
Traceability:

Decisions and justifications
are captured consistently
(not scattered across emails)



Consistency:

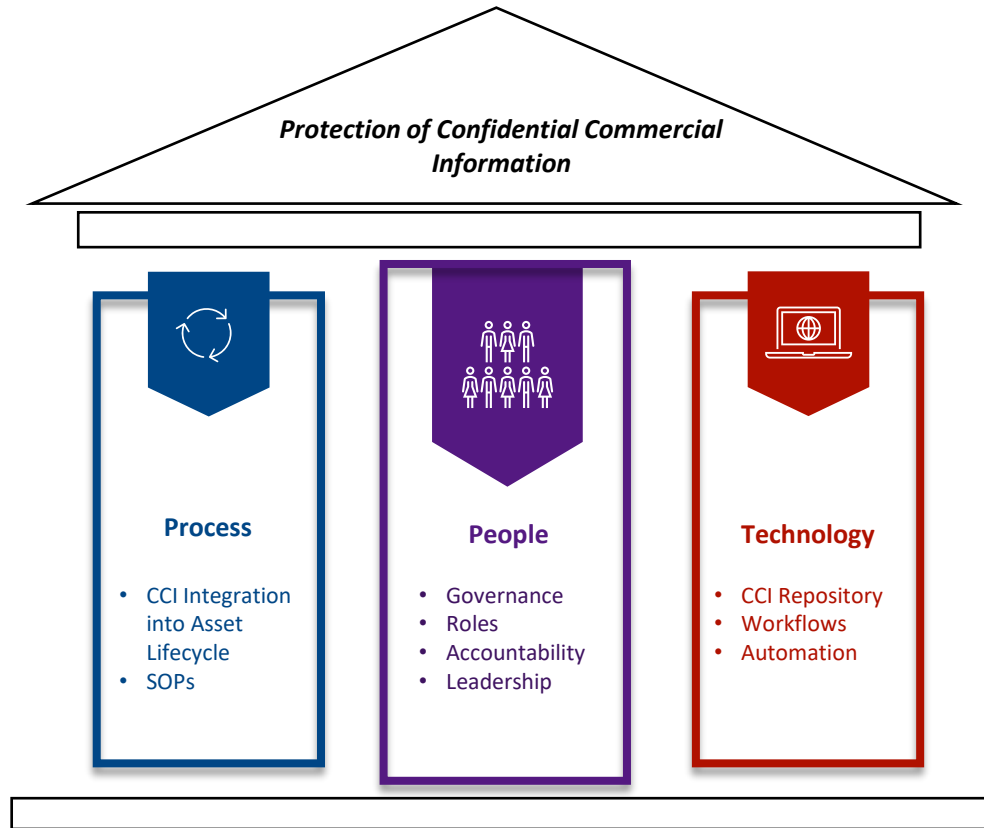
A governed CCI “source of
truth” reduces variability
across programs and stages



Efficiency:

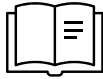
Standard workflows reduce
rework and cycle time –
enabling timely, compliant
public disclosure

Goal: Unified Cross-Functional CCI Alignment Model



CCI protection requires equal focus on **People**, **Process**, & **Technology**

Enabling a Unified Cross-Functional CCI Alignment Model



CCI Library Development and Governance

- Development of Asset Specific CCI Libraries
- Determine Library Governance



Unified Cross-Functional Partnership

- Strong functional foundations
- Promote understanding of CCI protection and why CCI Protection Matters



Coordinated Project Management & Oversight

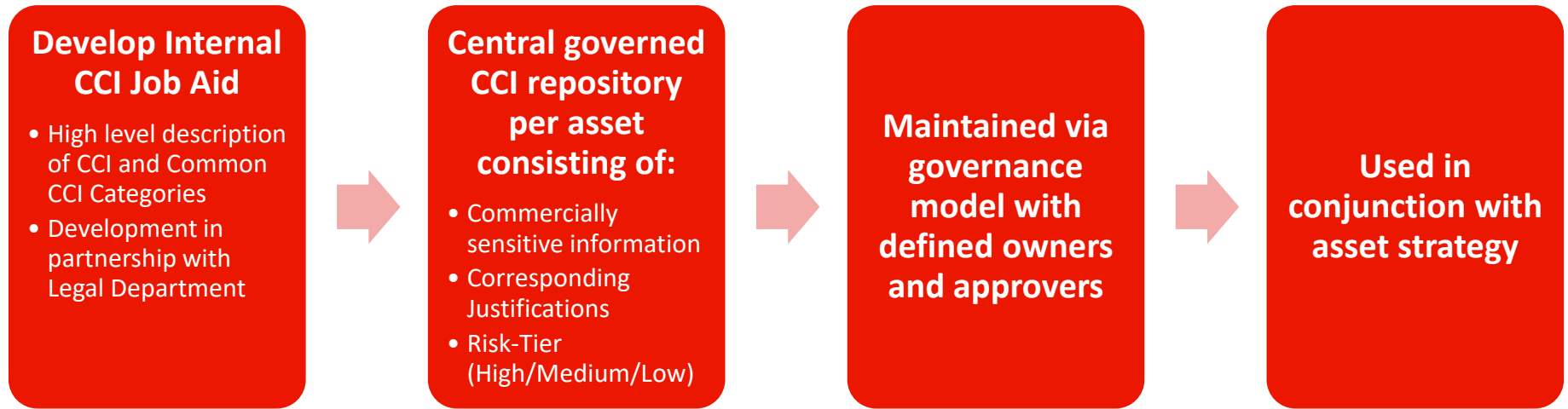
- Streamline Review Process
- Effective Reviewer Identification



Disclosure Request Management and Review Solution

- Integrated Platform for Request Intake, Review Workflows and Request Completion
- Dashboard Driven Oversight
- Automatic Notifications and Triggers

CCI Library Development and Governance



Think of the CCI library as our **brain** for what must be protected, linked to clear rules located in a secure central location

CCI Library Development and Governance: Strategic Goals

1. Reduce or Eliminate CCI in Document Development

- Libraries utilized at document development to **reduce or eliminate** CCI in draft documents

2. Standardize CCI Reviews

- Reviews at draft stage – **eliminate** CCI from our documents prior to finalizing
- Reviews at final stage – **due diligence** check for CCI

3. Use asset development planning, CCI job aid, CCI libraries, technology and automation to:

- Asset development planning used to assign **risk-tier**
- CCI libraries developed and maintained per asset using CCI job aid
- Utilize **process** and **technology** to ensure consistent protection of CCI

4. Prioritize CDTL and Patent Attorney time based on risk-tier and process

5. Improve Cycle Times, Less Rework, Better Protection

Risk-Tiering: Right-Size Review Rigor



Assess the Risk

Define Risk Tier

Assign Review Rigor

Disclosure Timing
Patent Status & Strategy
Asset Strategy
Risk Tiers: **High**, **Medium**, **Low**

High

First substantive public disclosures, pre-patent

Medium

Routine updates on established IP positions

Low

Standardized disclosures with limited IP exposure or no indication expansion

High

Full Team Review

Medium

Full Team Review

Low

Team Informed of technology enabled CCI identification

Disclosure Request Management and Review Solution

Create an improved document redaction request management solution that addresses the following needs:

1. Document Intake and Release

- **Standardizes** document intake and release across sectors and request types

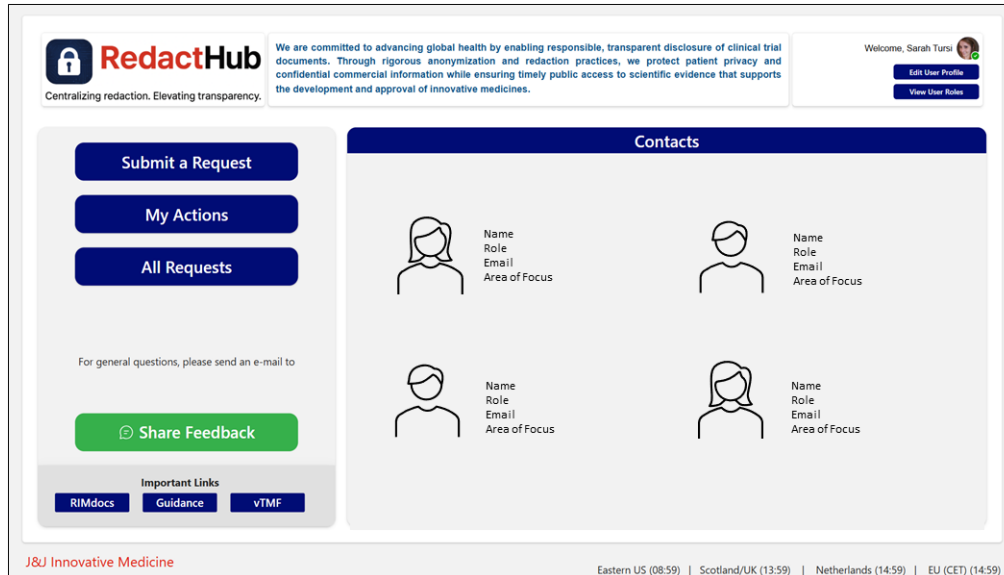
2. Review Oversight

- Enables advanced **planning** and end-to-end **oversight** of requests
- Efficiently **tracks** individual reviewer progress and completion with robust dashboards (enhanced **accountability**)
- Enhances **management** of requests and reviews through workflows and **automations** (ie, e-mails, dashboards, etc.)

3. Metrics and Capacity Management

- Enables effective **metric collection** and dashboard display
- Enables effective **management** of work across available **resources**

Disclosure Request Management and Review Solution: Review Oversight



Individuals have a **Personalized View** containing pertinent information relevant to their role:

- Requestors, Reviewers, Management, etc.

Review status will be tracked by **Category**:

- Request Level & Document Level
- Review Forecasting & Review Progress
- Completeness of Individual Reviewer
- Automatic Notifications and Triggers

Coordinated Project Management and Oversight

Partnership with Regulatory Project Management

Forecasting

- Anticipates future regulatory milestones and resource needs
- Supports proactive planning and alignment across all functions

Team Coordination and Monitoring

- Identifies Appropriate Reviewers
- Tracks progress against timelines and deliverables
- Identifies delays or risks early for timely intervention
- Establishes clear timelines and responsibilities

Risk Management

- Assesses potential risks to regulatory deliverables
- Implements mitigation strategies and escalation pathways



Unified Cross-Functional Partnership: Workshops

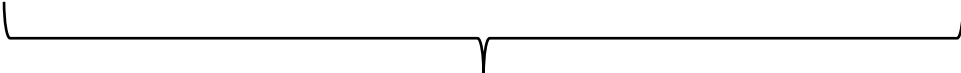
Engaged Discussions with Cross-Functional Partners

Project Management Oversight

- Disclosure Requirements
- Importance of CCI
- Roles and Responsibilities
- RPM Oversight & Management

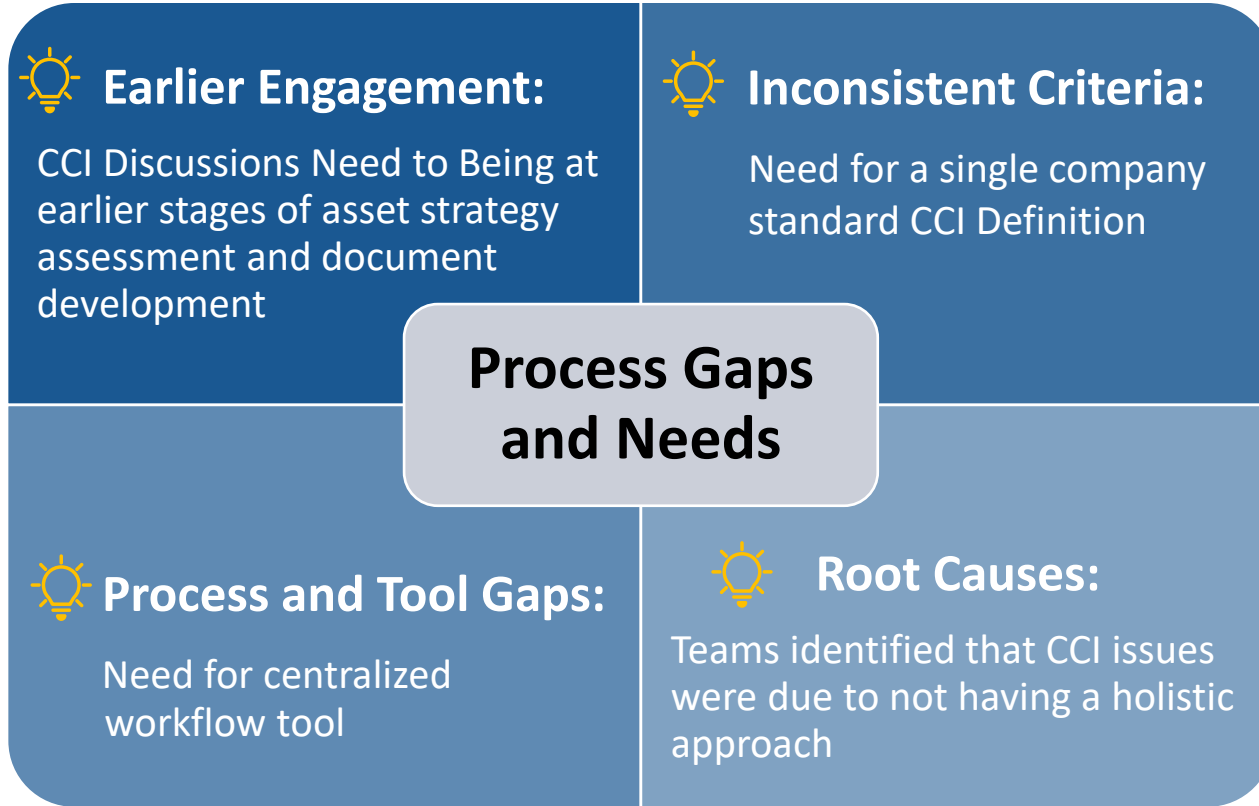
CCI Library Governance

- Finalize CCI Job Aid
- Define CCI Library Format and Storage
- Discuss CCI Library Governance
- Discuss Work Management System



Receive Feedback
Identify Opportunities for Growth
Build Process for Pilot Testing

Insights from Cross-Functional Workshops



"Need to remove CCI during protocol drafts and other draft documents"

"Is there a reference document to better help define CCI?"

"Too many emails, unclear roles, lack of tracking"

"Need to shift from a reactive to a proactive process"

Recommendations for Process Improvement



Process

- CCI Integration into Asset Lifecycle
- SOPs

Embed **CCI Awareness** Early in Development – Lean Authoring & Define CCI Strategy

Establish Clear **CCI Governance** – Ensure Accurate CCI and Team Responsibility

Maintain a Living **CCI Library** – Ensure CCI consistency across programs



People

- Governance
- Roles
- Accountability
- Leadership

Engage **Cross-Functional** Partners – It is a team effort!

- Engage Early
- Engage Often



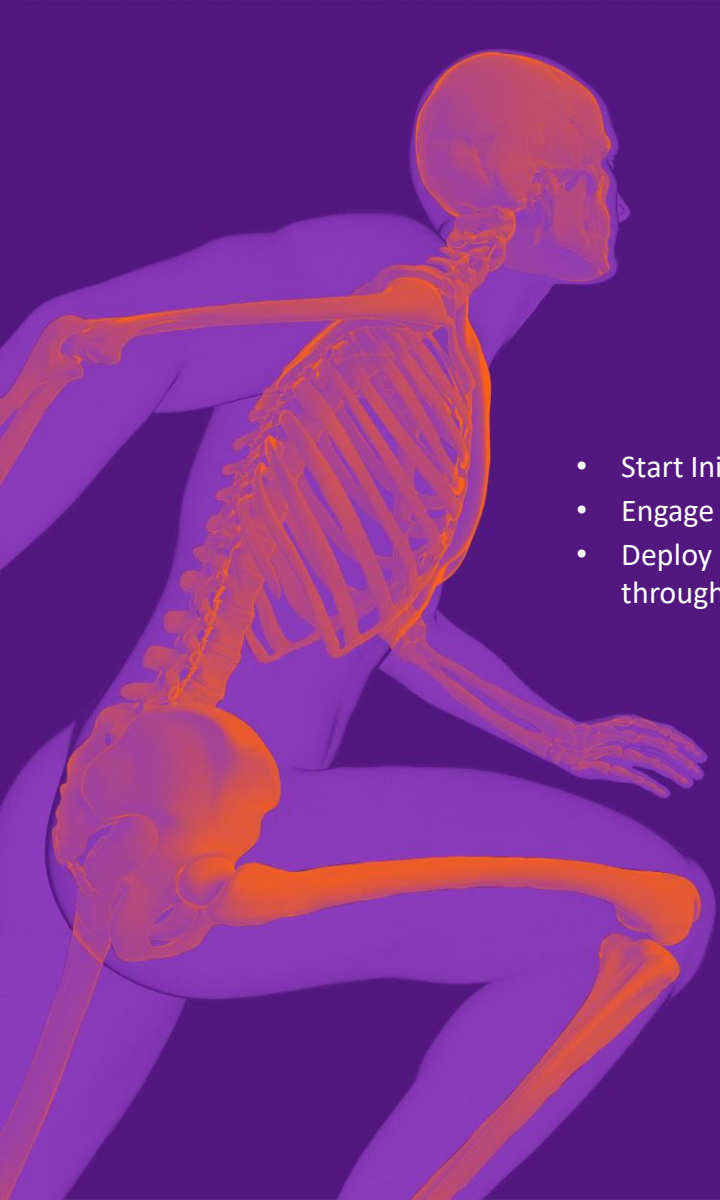
Technology

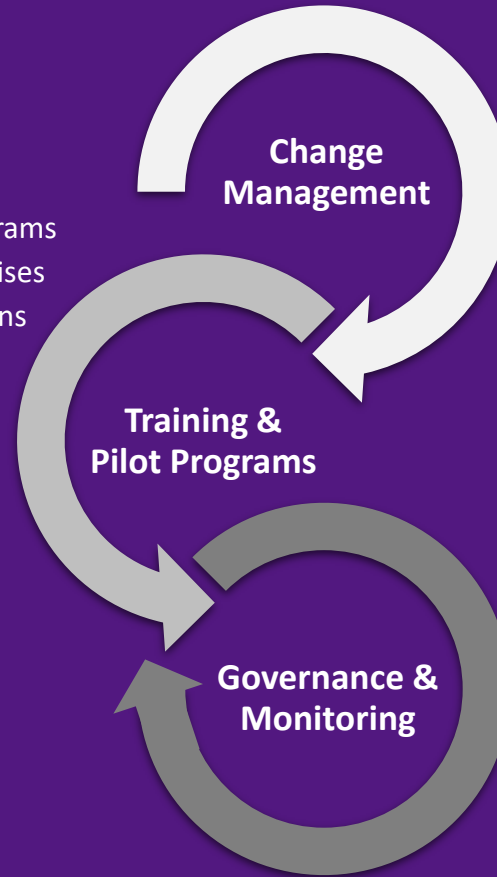
- CCI Repository
- Workflows
- Automation

Use Central **Tracking Tool** – Improve Review Management and Communications

Track **Metrics** – Ensure resources are being implemented efficiently

Implementation & Next Steps

- 
- Start Initial Pilot Programs
 - Engage Training Exercises
 - Deploy across functions throughout JnJ



- Assess the current process
- Engage Cross-Functional partners
- Secure Leadership
- Foster a culture of transparency across functions

- Develop Oversight Committees
- Track Metrics
- Implement Continuous Improvement

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Thank you & Questions

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