

Management of Commercially Confidential Information (CCI) Redaction In Contemporary Regulatory Submissions

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March 24, 2026

Disclaimer:

The views/opinions expressed in this presentation are those of my own and do not represent the views/opinions of Otsuka Pharmaceutical Development & Commercialization or any of its affiliates.

Objectives

1	Assumptions and Current Landscape
2	Information Sharing Across Development
3	Where CCI Lives End-to-End Lifecycle
4	Lifecycle Heat-Map: CCI Risk by Publication Type & Region
5	Product Development Information Sharing Strategies
6	Ultimate Goals

Transparency Assumptions and Current Landscape

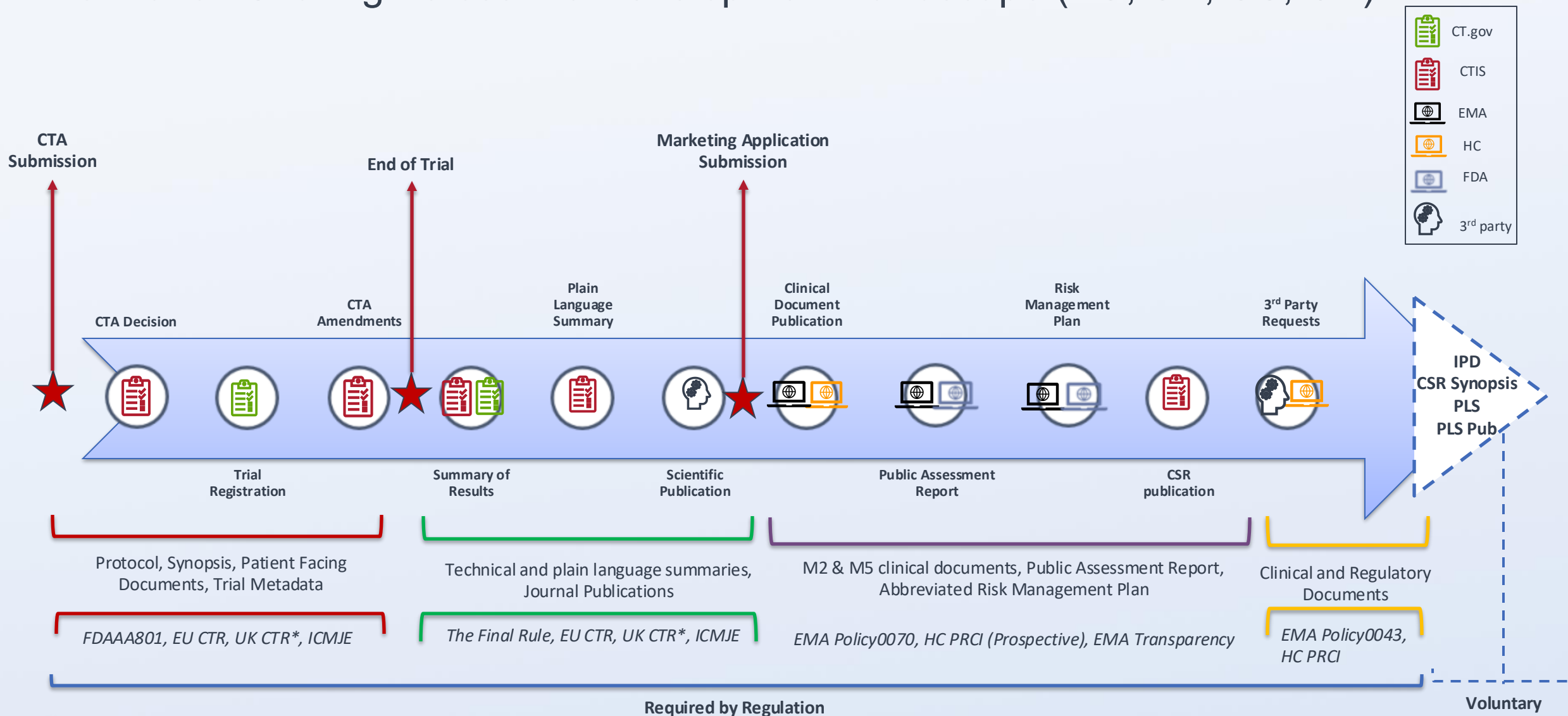
Assumptions

- **Commercially Confidential Information (CCI)**
 - Information that could undermine a company's economic interests if disclosed (e.g., manufacturing know-how, proprietary methods, supply chain, pricing/contractual terms)
- **Personal Protected Data (PPD)**
 - Information relating to an identified or identifiable individual; must be anonymized/pseudonymized as applicable
- **'Releasable-by-default'** stance increasingly promoted by regulators
- **Narrow, well-justified CCI** redactions are essential
- **Golden rule** = Author documents to be **disclosure-ready**; avoid embedding CCI where not strictly necessary

Current Landscape

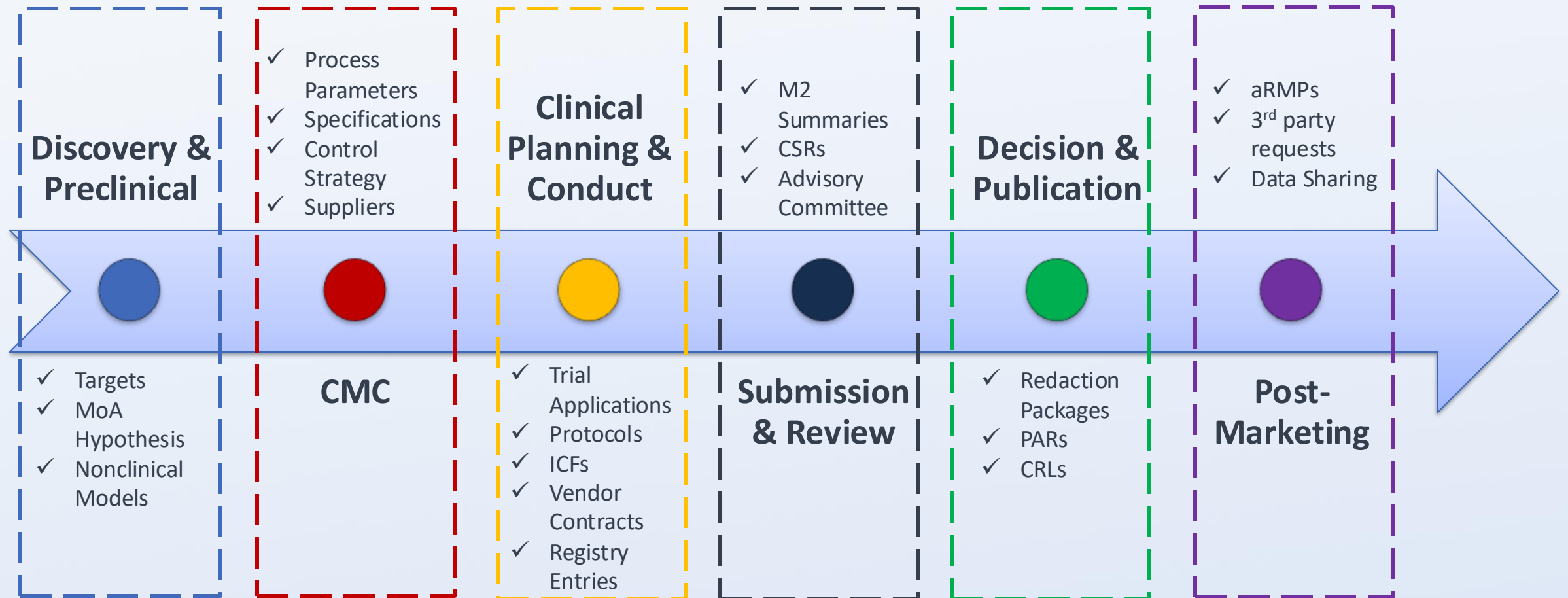
 EU	EU CTR/ CTIS: Earliest publication of protocol (ahead of trial start)
	Policy0070: Step 2 relaunch expands scope
	EMA Transparency: Publication of EPAR and aRMP
	Policy0043: 3 rd party requests for data
 US	CT.gov: Publication of protocol and SAP with results
	FOIA: 3 rd party requests for data
	FDA Advisory Committees
	FDA Complete Review Letters (CRLs)
 UK	UK CTR: Mandates registration, results, & PLS
 CA	ATI: 3 rd party requests for data
	PRCI: Proactive and on-request publication
 JP	Act No. 42: M1 & M2 for J-NDA; PMDA PAR

Information Sharing Across the Development Landscape (EU, UK, US, CA)



CTA = US IND; *UK CTR effective April 2026; Voluntary PLS = Generate PLS for every trial, regardless of regulation

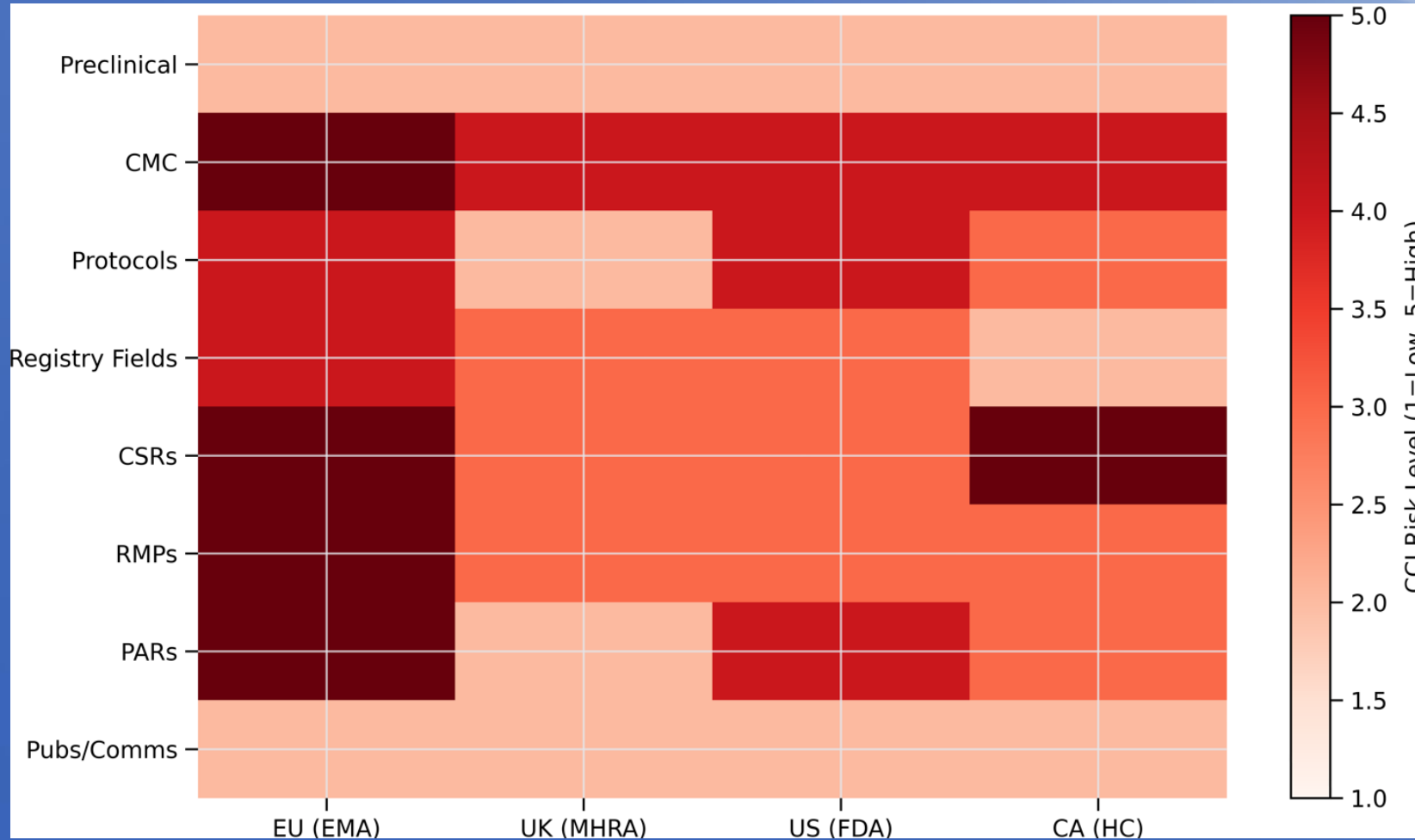
Where CCI Lives: End-to-End Lifecycle (EU, UK, US, CA)



MoA = Mechanism of Action; PARs = Public Assessment Reports; CRL = Complete Response Letters RMP = Risk Management Plan

Lifecycle Heat-Map: CCI Risk by Publication Type & Region

Timing + Breadth of what becomes public + Registry Workflows



What was measured?

CCI exposure risk for each document type and region uses two components:

- **Exposure:** WHAT becomes public; ~70% — How much content ultimately becomes public and the typical redaction allowances for CCI.
- **Timing:** WHEN it becomes public; ~30% — Earlier lifecycle publication/visibility increases practical risk (e.g., CTIS publication at decision/results vs. post approval)

Scoring: 3 questions for each row and region

1. Is publication required or routine?
2. How detailed is the public content?
3. Are redactions/withholdings permitted and used?

Lifecycle Heat-Map Scoring Definitions

RISK LEVEL	INTERPRETATION	TYPICAL IMPLICATIONS
1 – Low	Limited or controlled public exposure	Standard review; minimal CCI concern
2 – Low–Moderate	Public exposure but largely sponsor-curated	Routine CCI checks sufficient
3 – Moderate	Mandatory disclosure with defined scope	Targeted CCI positioning and consistency checks required
4 – High	Early or broad publication with limited deferral	Strong upstream controls and narrow, well-justified redactions
5 – Very High	Proactive publication of detailed content	Critical CCI risk; intensive governance and executive oversight

Product Development Information Sharing Buckets



3 main buckets in which CCI protection requires planning and strategy

Trial Lifecycle

Protocol Development & Registries

- Control or guidance during authoring
- Alignment of information across registries
- Appropriate redaction of documents

Marketing Applications

Health Agency Adjudication

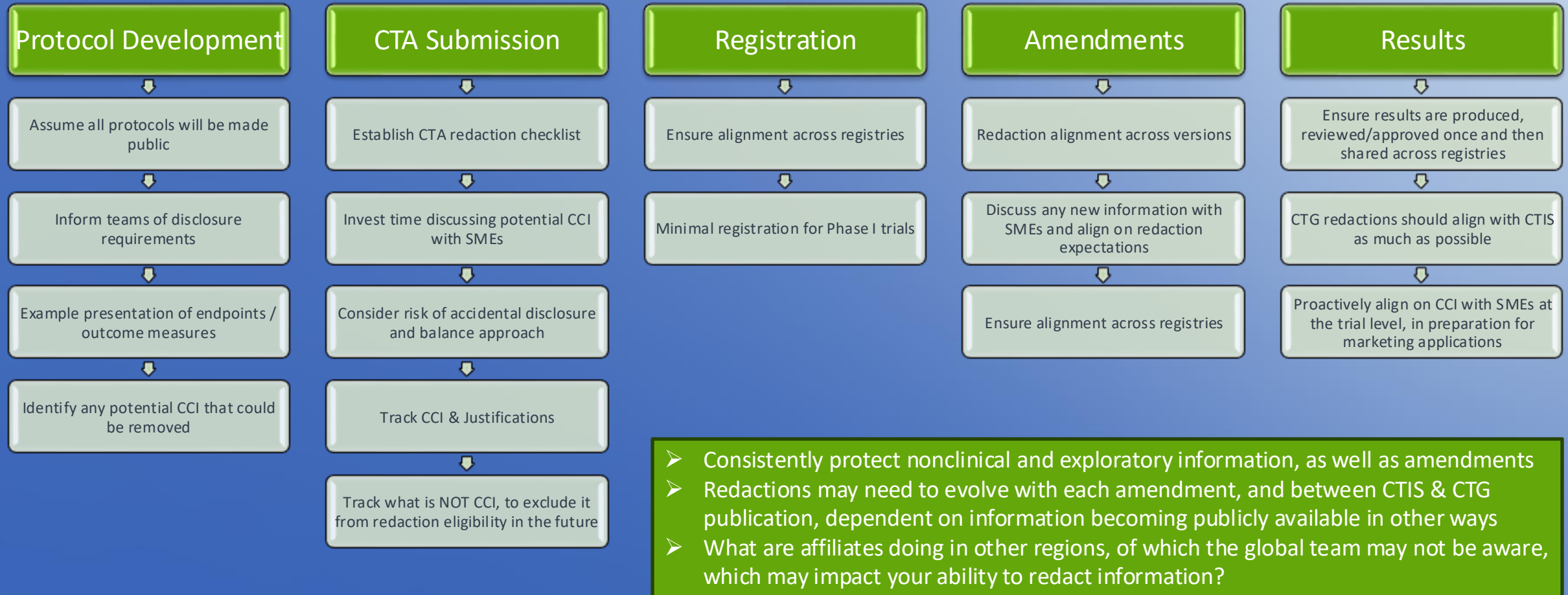
- Advisory committee materials
- Clinical and Regulatory document packages

Post-Marketing

Assessments & Requests

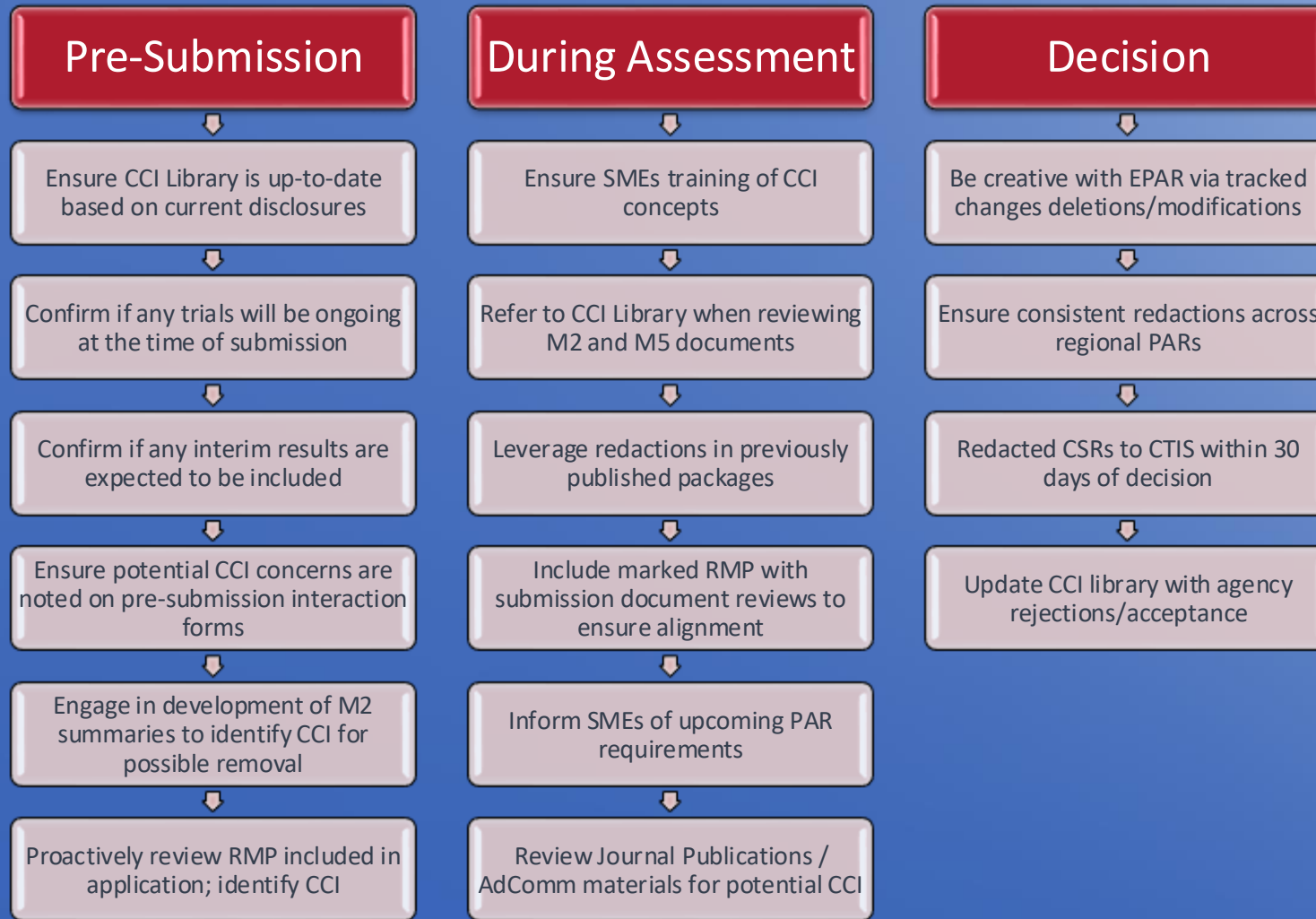
- Public Assessment Reports (PARs)
- Risk Management Plans (RMPs)
- Requests for information
- Data Sharing with Researchers

Trial Lifecycle



Continuously update CCI Library with each subsequent disclosure: Standard CCI, Aligned CCI, No longer CCI, & Justifications

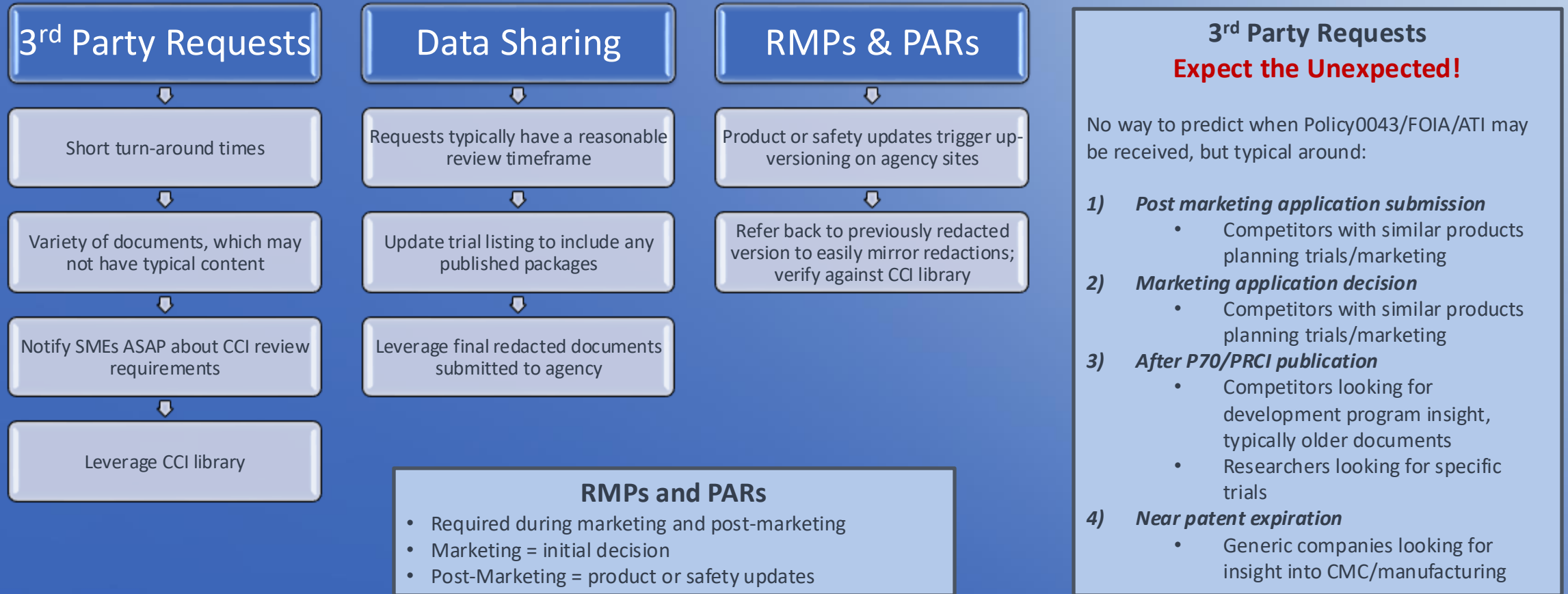
Marketing Application



- Strategy for blinded/ongoing trials/interim data included in marketing applications = High risk item
 - Rather than providing a heavily redacted document with minimal data utility, propose to agency delay of submission/ publication of redaction package until final CSR
- Leverage CCI accepted for redaction in prior packages
 - HC has continuously been publishing PRCI packages since 2019, while P70 was on hold
 - Re-purpose the redacted files and/or leverage the redaction justification for the current package
 - If EMA disagrees with proposals, leverage that information to challenge (if still not public)
- Creativity with EPARs
 - Unique opportunity to avoid redaction through deletion/ modification of text, prior to publication by EMA
 - Attempt to remove CCI directly (if justified) or reduce level of granularity
 - Withdrawn application = Opportunity to remove more information related to development background
- Maintaining an accurate CCI library throughout development, is the key to reducing CCI identification efforts and better supports conversations with SMEs and agency

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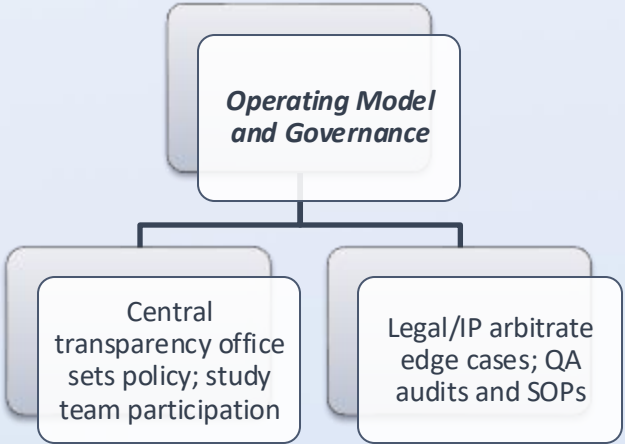
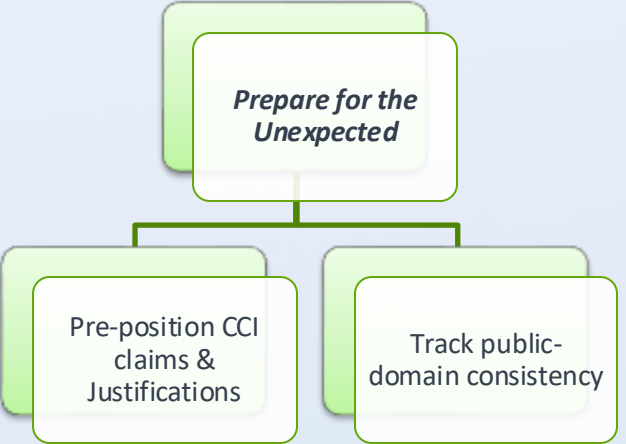
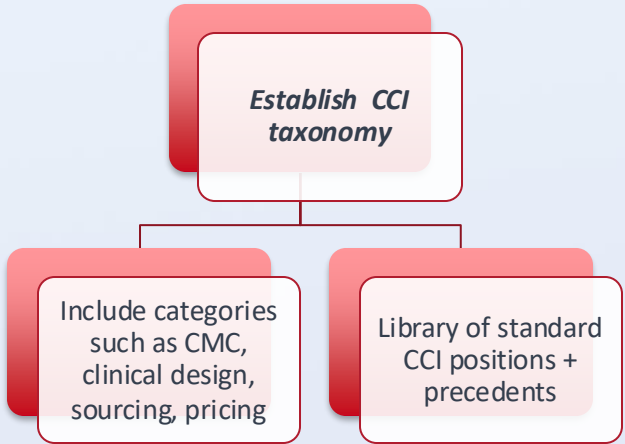
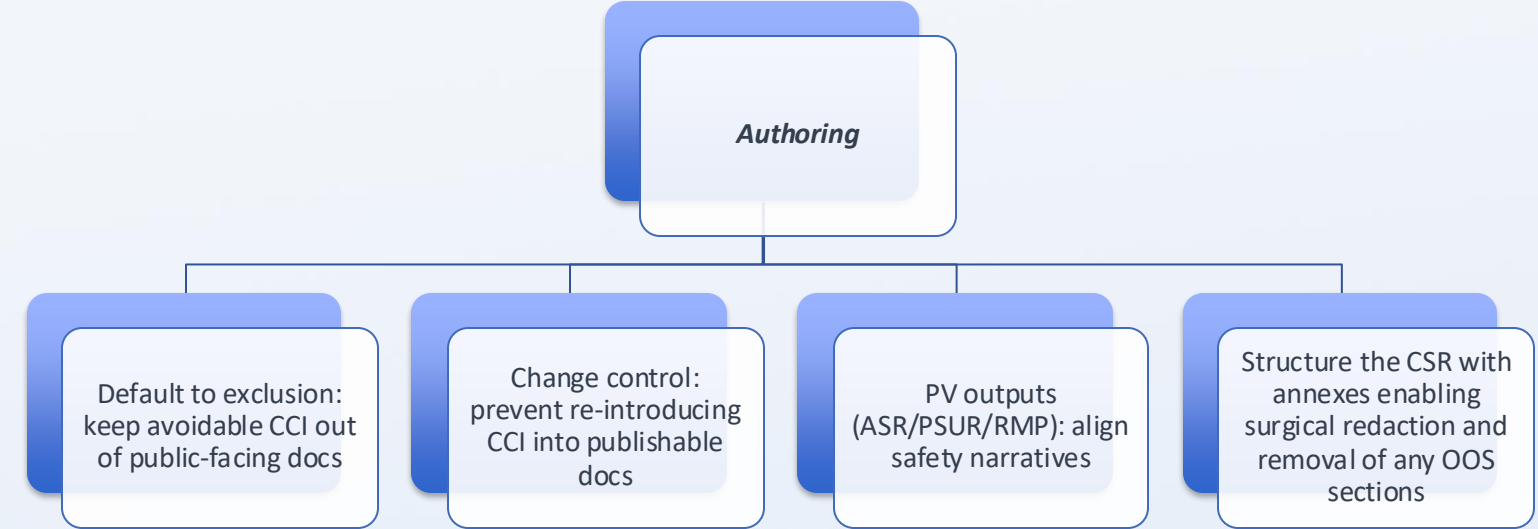
Post-Marketing



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Data Sharing = Data Sharing with Researchers

Ultimate Goals



Thank you for your attention,
please ask questions!