

# Meet the speaker

**Anaya Rehman** is a regulatory leader with more than a decade of experience spanning healthcare, academic research, and the pharmaceutical industry. As a medical doctor by training, she brings scientific depth and clinical insight to complex regulatory and transparency challenges.

At **Certara**, she provides strategic and technical leadership to the clinical trial transparency and disclosure team, advising global sponsors on compliance with evolving global clinical disclosure regulations. She is known for translating regulatory requirements into practical, risk-based strategies that enable both compliance, operational efficiency, and responsible integration of AI-enabled solutions.

Anaya is an avid speaker and thought leader in regulatory affairs, frequently presenting at industry conferences and professional forums on clinical trial transparency, disclosure strategy, and the evolving role of AI in regulatory innovation.





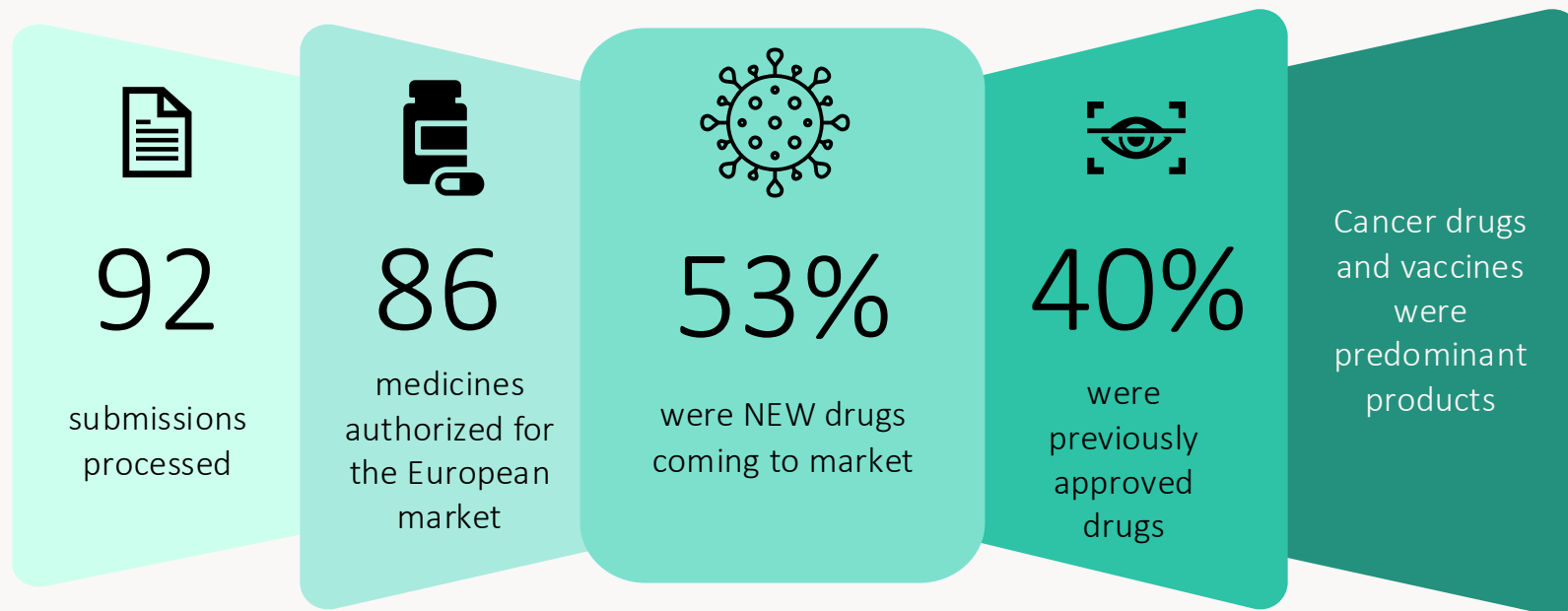
# Policy to Practice: A Compliance Checklist for EMA Policy 0070

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Austin, Texas

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**CERTARA**

# EMA Policy 0070 Submissions: 2025 Trends



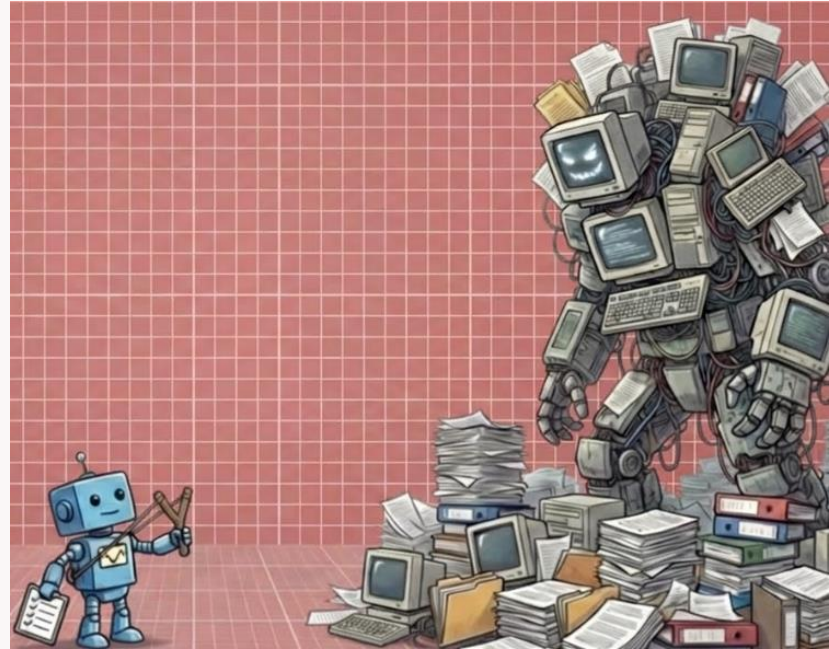
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# The David vs Goliath of Compliance

Big Pharma brings teams and automation.  
Smaller companies bring one hybrid role.

The EMA brings the same expectations.

The advantage isn't size.  
It's having a playbook.



# Why We Fail: Common Pitfalls

*The rules are clear. Execution breaks.*



**Ownership void**  
Everyone involved,  
no one accountable



**Inconsistency**  
Inconsistent  
redactions across  
documents



**CCI Overreach**  
Too many  
redactions, not  
enough justification



**Lost purpose**  
Redactions that  
eliminate scientific  
value

# EMA Policy 0070 Submission Readiness Checklist

*A Structured Approach to Compliance*



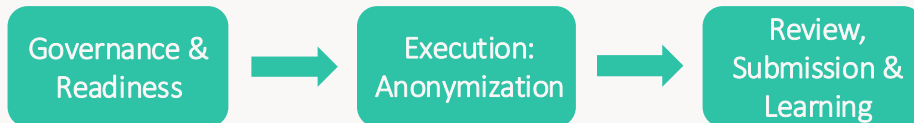
- Regulatory assurance: Minimizes rework, rejections, and follow-up inquiries
- Operational efficiency: Decisions made upfront, reducing downstream effort
- Risk mitigation: Defensible protection of patient privacy and company IP

The screenshot shows a document titled "EMA Policy 0070 Submission Readiness Checklist" with a red header. It is divided into two main sections, each with a red header: "Governance and planning" and "Document identification and collection". Each section contains a list of tasks with checkboxes.

| Governance and planning                                                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Assign a Policy 0070 Project Lead and cross-functional team (Regulatory, Clinical, Data Privacy, Legal, Medical Writing, Transparency & Disclosure). |
| <input type="checkbox"/> Review EMA Policy 0070 guidance along with any applicable internal SOPs or guidance documents.                                                       |
| <input type="checkbox"/> Establish timelines aligned with EMA Policy 0070 guidance.                                                                                           |
| <input type="checkbox"/> Confirm scope of submission.                                                                                                                         |
| <input type="checkbox"/> Consider joint submission with Health Canada, if applicable.                                                                                         |
| <input type="checkbox"/> Engage anonymization team and align on service procedure.                                                                                            |

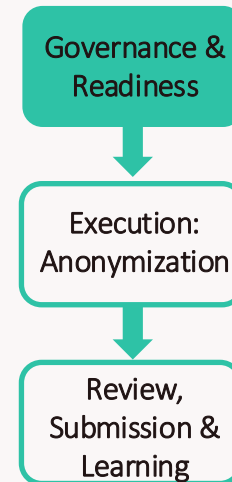
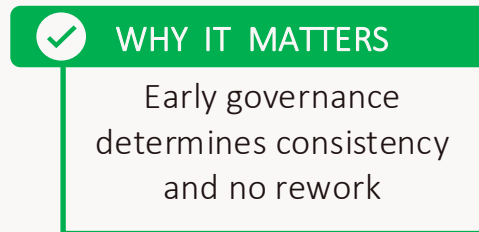
  

| Document identification and collection                                                                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Review List of Expected Documents (LED) (sent with Invitation Letter).                                                               |
| <input type="checkbox"/> Collect all clinical reports in scope: (Section 5.7, <a href="#">External Guidance on the implementation of Policy 0070 (v1.5)</a> ) |
| <input type="checkbox"/> Ensure documents are in PDF format.                                                                                                  |
| <input type="checkbox"/> PDF files should not exceed 200 MB. If splitting (or merging) of documents is required, confirm                                      |



# Governance and Readiness

- Assign clear ownership and cross-sectional governance
- Align scope, timelines and EMA Policy 0070 guidance
- Engage transparency expertise upfront
- Align early with EMA – pre-submission meeting, LED and strategy



# Execution: Anonymization

- Identify and collect all in-scope documents and datasets
- Define and apply the anonymization strategy (qualitative or quantitative)
- Perform re-identification risk assessment and QC
- Apply CCI redactions sparingly, with defensible justifications
- Build consistency through libraries and standardized templates



## COMMON FAILURE

Inconsistent  
anonymization, over-  
redaction and unmet re-  
identification thresholds



## WHY IT MATTERS

Failure to protect privacy  
leads to regulatory  
rejection, data breaches  
and loss of trust

Governance &  
Readiness



Execution:  
Anonymization



Review,  
Submission &  
Learning

# Review, Submission and Learning

- Prepare and submit Redaction Proposal and Final Redacted packages
- Respond clearly and consistently to EMA feedback
- Ensure eCTD readiness at every stage
- Archive all materials and capture lessons learned to improve the next cycle



## COMMON FAILURE

Incomplete submission package, delayed responses to EMA



## WHY IT MATTERS

Effective submission and post approval management are critical for maintaining regulatory compliance

Governance & Readiness



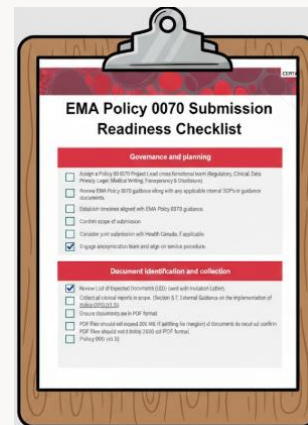
Execution: Anonymization



Review, Submission & Learning

# Key takeaways

- EMA Policy 0070 Submission Readiness Checklist supports consistent execution of regulatory policy.
- Structured playbook minimizes reactive compliance.
- Front-loading preparation saves significant time in the final regulatory review stage.



# Thank you!

**Anaya Rehman**, MBBS, MSc  
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*Let's continue the conversation...*



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