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Policy to Practice: A Compliance Checklist for EMA Policy 0070

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ABSTRACT

EMA Policy 0070 mandates the publication of clinical data with the goal of increasing transparency while protecting patient privacy and commercially confidential information. Despite its clear intent, implementation remains complex. Compliance with EMA Policy 0070 remains challenging due to gaps in governance, inconsistent document quality, and weak anonymization and CCI management, often leading to delays and increased regulatory risk. This paper identifies common compliance pitfalls, such as the ownership void, CCI overreach, and inconsistency, and proposes a structured submission readiness or a compliance checklist. This 'playbook' approach serves as a critical tool for organizations without dedicated teams, ensuring regulatory compliance, preserving scientific integrity, and protecting patient privacy and intellectual property.

INTRODUCTION

The implementation of the European Medicines Agency (EMA) Policy 0070 [1] represents one of the most significant shifts in global clinical data transparency. Originally designed to foster public trust and enable secondary scientific research, the policy requires the publication of clinical reports supporting marketing authorization applications. Following a restart of the policy implementation in late 2023, the scope of transparency has widened, demanding more rigorous anonymization and justified redaction proposals. In 2025 alone, 86 medicines were authorized for the European market, with supporting clinical data systematically published via the portal [2]. Statistical analysis reveals that 53% of these were new medicines entering the European market, while 40% involved previously approved products, underscoring that disclosure obligations persist well beyond initial

authorization [2]. Furthermore, cancer therapies and vaccines constituted the largest share of products undergoing disclosure.

Recent research into industry practices reveals a stark contrast in how organizations approach these requirements. While the workload and regulatory expectations remain consistent across the board, the resources available to meet them vary drastically. Larger organizations often leverage dedicated transparency teams and sophisticated automation to manage the volume. In contrast, smaller companies frequently lack specialized tools and sufficient personnel, leaving a few individuals to "wear multiple hats" and handling everything from document collection and risk assessment to making complex, defensible redaction decisions.

This resource disparity is why a repeatable, structured playbook is essential for lean environments. It effectively fills the gaps left by limited staffing and provides small teams with a clear route to high-quality, defensible submissions. Much like the classic story of David and Goliath, where a young shepherd defeats a giant not through size or heavy armor, but by utilizing the right tools and a precise approach. Success in compliance is determined by strategy rather than scale. Ultimately, the advantage does not stem from the size of the company, but from having a consistent playbook, in other words a compliance checklist or more aptly a submission readiness checklist [3] that guides critical decisions and keeps the submission process on track.

WHY WE FAIL: COMMON PITFALLS IN EXECUTION

Even with the clearest regulatory guidance, execution often breaks down. Failure is rarely due to a lack of intent, but rather due to systemic organizational issues and technical missteps.

Ownership Void

One of the most frequent organizational failures is the ownership void. Because Policy 0070 touches multiple functions [4] - Regulatory, Clinical, Legal, Clinical Disclosure, and IT - it is common for everyone to be involved but no one to be truly accountable. This lack of a single process owner results in late engagement of transparency expertise, unclear scope definitions, and a failure to align the submission strategy with the overall regulatory timeline. Once a designated lead is identified, they need to reconcile conflicting demands of all stakeholders.

CCI Overreach

Commercially Confidential Information (CCI) redaction remains a contentious part of the submission process. Sponsors often default to an over-redaction strategy, attempting to

hide significant portions of the document without providing specific justifications. The EMA has explicitly stated that data in the public domain cannot be redacted as CCI. To ensure compliance, each redaction must be supported by a robust justification explaining how disclosure would specifically undermine the applicant's economic interests [5]. Overreach in this area often leads to multiple rounds of regulatory queries.

Inconsistency

Inconsistency in the anonymization strategy across documents is a major red flag for reviewers. This fragmentation poses a critical risk to the protection of personal data, as a specific piece of information may be redacted in one section of the dossier while remaining visible in another summary document [4]. Without a centralized redaction library or a robust Quality Control (QC) process, these discrepancies lead to concerns about the overall integrity of the anonymization strategy.

Lost Purpose

The ultimate goal of Policy 0070 is to provide data that has scientific utility [6]. Some sponsors apply anonymization techniques so aggressively that the resulting document loses its 'purpose' by becoming unusable for secondary research. This is an important requirement that needs to be considered carefully when selecting the anonymization methodology [1]. Redactions that eliminate scientific value defeat the spirit of the transparency mandate.

THE EMA POLICY 0070 SUBMISSION READINESS CHECKLIST

To ensure a seamless transition from policy to practice, organizations must adopt a structured and iterative approach. For the sake of understanding this article, we have divided the submission readiness checklist into three distinct parts: Governance and Planning, Execution and Anonymization, and Review, Submission, and Learning. The entire checklist is available upon request.

Part 1: Governance and Planning

Success in the final submission stage is determined by the quality of preparation in this initial phase. Organizations should focus on assigning a Policy 0070 project lead who holds cross-functional authority to avoid the ownership void. This phase requires building a multi-disciplinary team encompassing regulatory, clinical, legal, and clinical disclosure experts. Early alignment with the EMA through pre-submission meetings and a finalized List of Expected Documents (LED) is crucial to establish realistic timelines and confirm the scope of the submission, ultimately preventing expensive late-stage rework.

Part 2: Execution and Anonymization

The execution phase involves the technical application of the transparency strategy. Organizations must identify and collect all in-scope reports, ensuring they are in high-quality, searchable PDF formats. A critical decision in this part is defining the anonymization strategy - choosing between a qualitative, rule-based approach or a quantitative, risk-based methodology. To combat CCI overreach and inconsistency, a centralized CCI library of justified redactions should be maintained. Adhering to good transparency practices [7], rigorous multi-level QC and re-identification risk assessments are essential to ensure the final package protects patient privacy without sacrificing data utility.

Part 3: Review, Submission, and Learning

The final part focuses on the mechanical and iterative aspects of the regulatory submission. This involves preparing the Redaction Proposal Document Package (RPDP) and the corresponding justification table for EMA review. Organizations must be prepared for responsive interaction, addressing regulatory feedback clearly and consistently. Maintaining electronic Common Technical Document (eCTD) readiness throughout ensures a smooth upload to the portal. Crucially, this part includes an archiving and learning component where strategy documents and EMA feedback are captured to refine the playbook for future regulatory cycles, transforming compliance from a reactive task into a repeatable institutional strength.

CONCLUSION

The era of reactive compliance in clinical data transparency is officially over. As evidenced by the 2025 EMA Policy 0070 trends, transparency is now an immutable pillar of the European regulatory landscape. While resource disparities between 'David and Goliath' organizations persist, a structured compliance checklist levels the playing field. Front-loading preparation through a three-part playbook saves significant time, minimizes the risk of regulatory rejection, and preserves the scientific integrity of clinical data. By embracing a structured approach, organizations not only fulfill their regulatory obligations but also uphold their commitment to public trust and the advancement of global medicine.

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