Introduction to the Role of Transparency Writers in the Validation of Transparency Platforms

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This presentation is incomplete without accompanying verbal commentary.

Agenda

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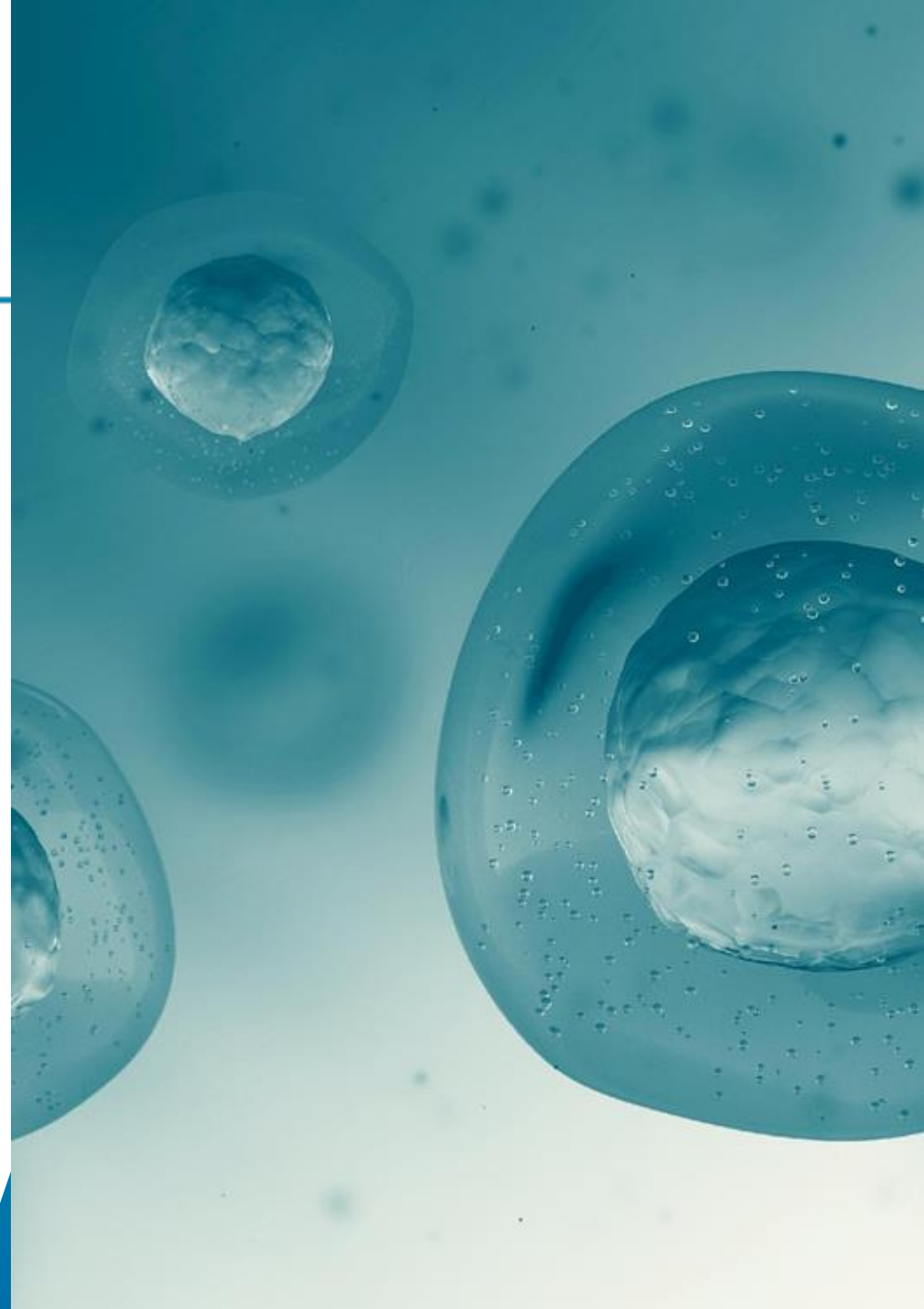
- Why Validation Matters?
- What Medical Writers Uniquely Understand?
- Evolving Role of Medical Writers in Validation
- The Platform Lifecycle
- Contributions Across the Validation Lifecycle
- Closing Remarks and Way Forward



Introduction

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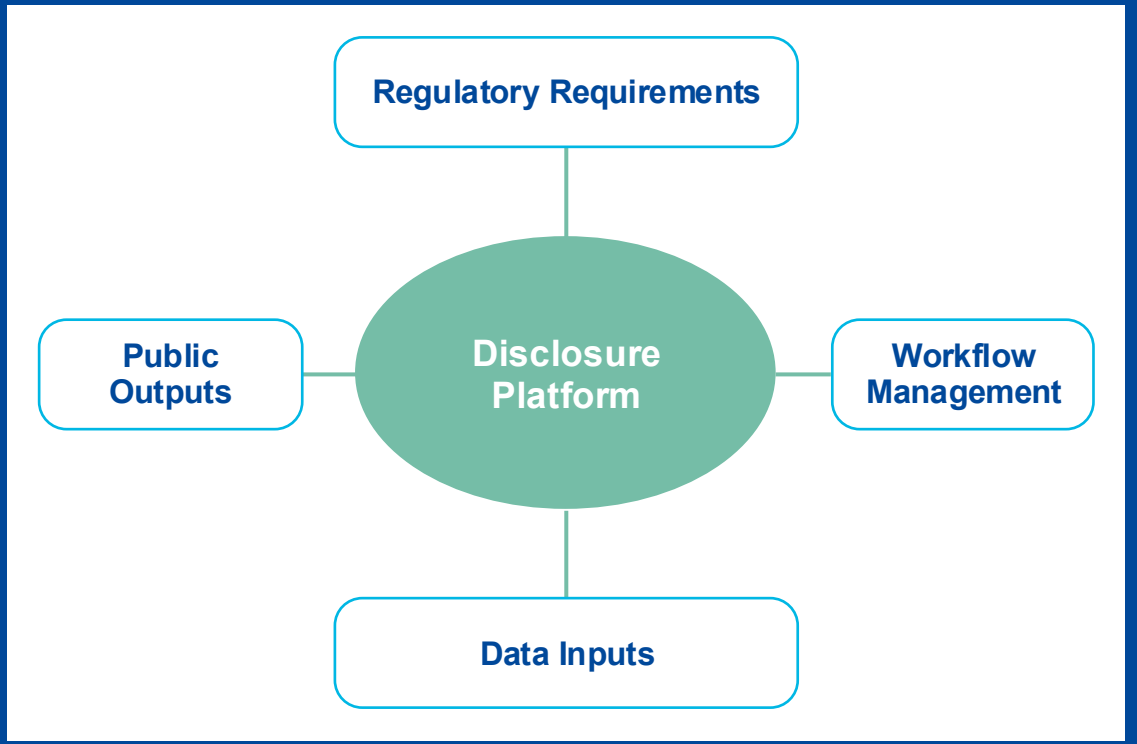
Validation

The process of checking whether a system is fit for its intended business use.

User Acceptance Testing (UAT)

How an end user validates whether the system works as intended in real-world workflows.

Disclosure Platform — The Intersection Point



Validation today is not only a technical requirement — it is a critical quality measure ensuring checks and balances.

Why Validation Matters?

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1

Regulatory Compliance & Quality

Directly impacts compliance obligations and the quality of disclosure deliverables.

2

Workflow Management

Ensures consistency in disclosure operations and platform behaviour.

3

Business Compliance

End-user-side validation identifies business- and policy-specific gaps that generic vendor testing can miss.

Validation directly shapes compliance, consistency and the quality of every public disclosure deliverable.

What Medical Writers Uniquely Understand?

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1

Disclosure Regulations

Laws and disclosure requirements across global registries.

2

Disclosure Deliverables

Registrations, amendments, status and site changes, and results.

3

Review Criteria

Database-specific checks, such as NIH review criteria.

4

Data and Platform

How structured data flows into published outputs.

Medical writers bridge the gap between regulatory expectations and platform behaviour.

Evolving Role of Medical Writers in Validation

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How We Contribute

1. **Real-World Expertise**
   Hands-on experience with disclosure deliverables and regulations.

2. **Define and Design**
   Shape templates, decision trees and workflow logic.

3. **Strengthen Systems**
   Support development teams in building robust, compliant platforms.

Role Evolution

From
Authoring and document-focused work

To
Strategic validation partner

The Platform Lifecycle

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Validation runs across the whole platform lifecycle, not just at go-live.

Phase 1 — Implementation

Initial Build and Deployment

- Requirements gathering and system design
- First-time configuration of workflows and templates
- Full UAT before the platform goes live

Phase 2 — Maintenance

Upgrades, Hotfixes and Enhancements

- Scheduled upgrades and version releases
- Hotfixes for defects found in production
- New enhancements driven by regulatory change

Both phases need medical writer input — each release can change how disclosure outputs are produced.

Contributions Across the Validation Lifecycle

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1. Plan

Set expectations and define business requirements.

2. Design

Shape templates, workflow logic and decision trees.

3. Test

Run UAT and QA scenarios in the test system.

4. Defects and Retest

Assess impact, clarify expected outputs, retest fixes.

Regression

Re-running existing, previously working scenarios after a change, to confirm that new builds or fixes have not broken established disclosure workflows.

Closing Remarks and Way Forward

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Validation succeeds when medical writers are embedded as active quality partners — not treated only as end users.

Way Forward

1

Get Involved Early

Bring writers into requirements review and test design from the start, not at UAT sign-off.

2

Define Showstoppers

Agree upfront which defects block release, based on compliance, data quality and usability risk.

3

Design Real Scenarios

Build validation around real disclosure workflows, including exceptions and late-breaking changes.

4

Continuous Improvement

Treat every release as a learning loop feeding platform enhancements, training and process updates.

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THANK YOU!

Questions?

Thank you — happy to take your questions