



Real Life Sciences

May 2, 2022 14:00

How Disclosure Teams Are Collaborating And Embracing the Changes Imposed by Global Transparency Regulations

US Connect 2022



1. Trends in Global Disclosure
2. Disclosure & Transparency Teams in the Spotlight
3. Adapting to the New World





Sponsors are facing a common set of challenges to balance regulatory and internal policy expectations while mitigating the risk of re-identification of patient data and company confidential information.

Regulatory Needs

Navigating regulatory **requirements** are complex

New regulation rollout
e.g.; Eu **Reg 536/2014** CTR
in 2022

Quantitative risk
assessments uncharted
territory for most
manufacturers

Voluntary Sharing Requirements

Separate process for prep of
voluntary disclosures

Lack support for
**interchangeable and
reusable** CSRs and synopses
across voluntary and
regulatory

Lack a proactive and
quantitative anonymization
approach for datasets

Resource Skills & Constraints

Constrained teams are
challenged to support
increase in demand

Data and docs are
often managed in
organizational **silos**

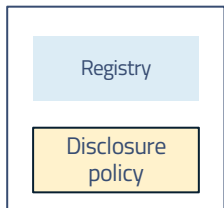
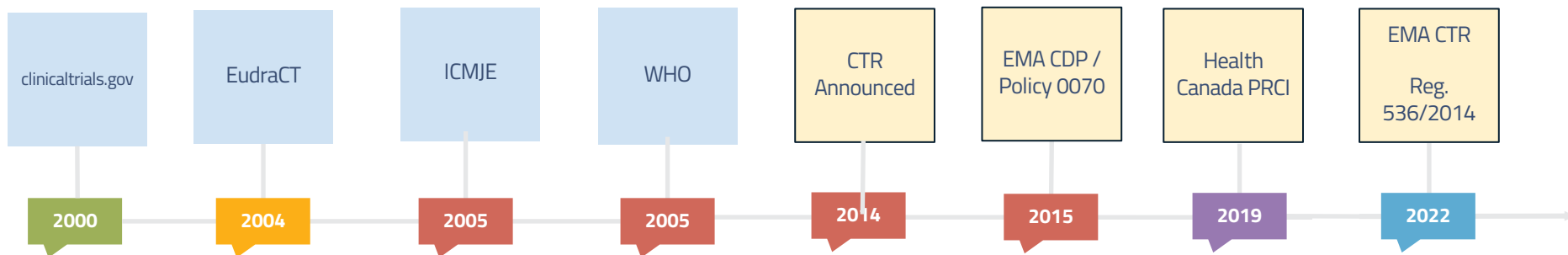
Quantitative vs.
qualitative **skills**

Timelines & Scalable Processes

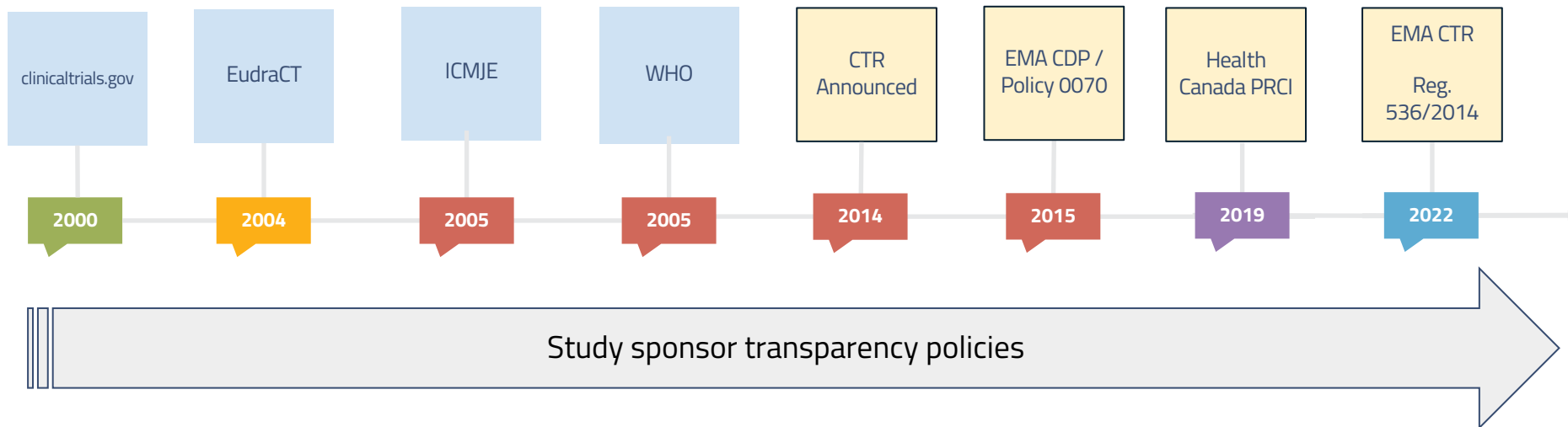
Desire a **repeatable and
reusable** quantitative risk
modeling methodology and
tech

Disclosure teams becoming
the **bottleneck** as result of
new regulations

Manual **redaction** is
slow, arduous
and error prone and adds
risk



- Timing and content details of registration varies (registration, results, etc)
- Clinicaltrials.gov most popular – often used in support of trials conducted globally
- Requirements for each disclosure policy/regulation varies



- Publicly available sponsor specific transparency policies
- Describes what is shared and when - some more detailed than others
- Common examples: Clinical Study Reports, Synopses, Datasets...



Health
Canada



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



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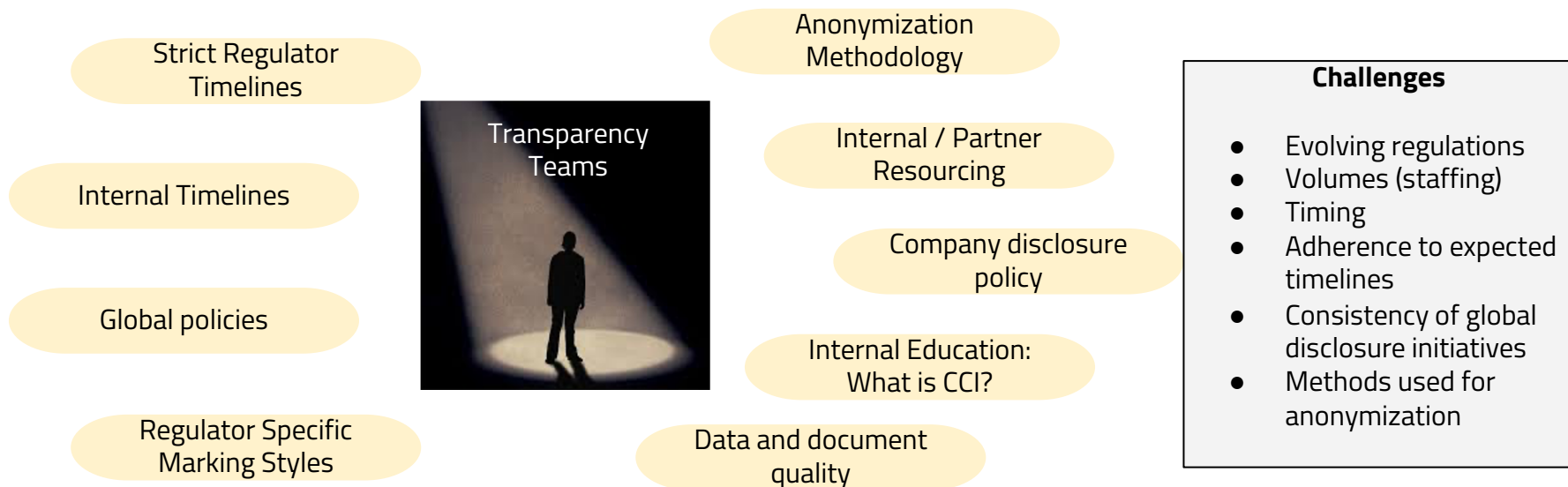


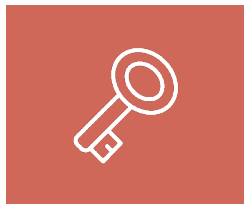
Pharma.com
+ Voluntary

Regulation / Policy	PRCI	CTR	Policy 70	Clinicaltrials.gov + Other registries	Company Transparency Policy
Scope	Clinical summaries, CSRs, Anonymization Report	CTA, IBs, protocol, CSR, Technical Summary and more!	Clinical summaries, CSRs, Anonymization Report, Sample CRF, SAP, Protocol	Protocol and SAP	CSRs, Synopses and Pt. Level Datasets
Methodology	Quantitative Anonymization	At discretion of the trial Sponsor	Quantitative Anonymization	At discretion of the trial Sponsor	At discretion of the trial Sponsor
Status	Live	Live	Temp hold (Brexit/COVID)	Live	Live
Submission Requirements	Prospective and retrospective (on request)	New trials as of Jan 2023 All active trials as of Jan 2025	All marketing authorizations starting Jan 2015	2000	N/A
Mark Style Requirements	Names: redact Overlay text vocabulary: PI/CBI	At discretion of the trial Sponsor	Names: retain PI and signatory names Overlay text vocabulary: PPD/CCI	Overlay text vocabulary: PII/CCI	At discretion of the trial Sponsor

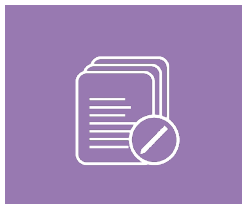


Never before have Disclosure & Transparency teams found themselves more squarely the center of the clinical process and balancing the various needs of regulators and internal policies. Collaboration between Disclosure/Transparency and Medical Writing, Regulatory, Legal, Biostats and Clinical teams is an absolute requirement to the organization's success.

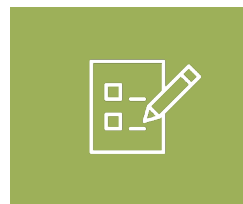




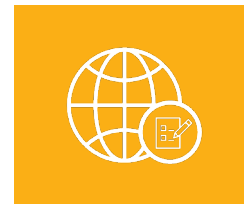
Personal data and commercial confidential information are exempt from disclosure



Even in the case of a deferral request, public and non-public version documents must be submitted simultaneously



Member States (MSCs) will issue their decision regarding the CTA in CTIS



Following a decision (of any kind) by Member State(s), public version data and documents will be made available to the public in CTIS - unless a deferral was requested and approved



1

Each document will be submitted in anonymized / redacted form ("for publication") and unredacted form ("not for publication") simultaneously.

2

Example documents for publication include but are not limited to:

- Protocol
- Investigator Brochure
- Informed Consent Information Sheet

3

Expectation is for sponsors to submit high quality dossiers in CTIS to minimise need to raise RFI.

Document	Public	Non-Public
Initial Clinical Trial Application	✓	✓
Protocol	✓	✓
EU CT Form	✓	✓
Multi-Trial Substantial Modification form	✓	✓
Investigator Brochure	✓	✓
Informed Consent Information Sheet	✓	✓

Listing represents a subset of documents. Please refer to EMA [LINK](#) for more details

Consideration	Process Impact	Solution Options
End to end disclosure requirements throughout the trial process - CCI and personal information	Preparation of public facing documents which protect personal and commercial confidential information must occur throughout the trial process . Consider timing expectations and coordination with internal teams such as medical writing, legal and regulatory.	Prior to your first CTIS study, conduct internal process mapping and define a cohesive communication between medical writing, regulatory, legal, disclosure, safety, clinical operations
Simultaneous submission of public and non-public version documents	Document anonymization for public facing materials is now the critical path of the trial process. Tools, timing and processing volumes must be considered to support the trial process within CTIS.	Consider fit-for-purpose anonymization technology for fast and efficient anonymization to maintain pace and quality; engage expert provider for help (think RLS!)
Roles & responsibilities including 3rd parties using CTIS	CTIS is new for everyone. Consider training needs, roles, best practices and business decisions such as deferrals with respect to managing the end to end process in CTIS. If you have a CRO engaged, what role will they fill on your initial CTIS studies vs. your own teams?	Form a cross-functional task force for navigating the first trial on CTIS and building an internal knowledge base for your business processes/decisions
Consider change impact and consistency across trials, registries and platforms	Consider consistency of global business decisions regarding what is disclosed vs. masked in clinicaltrials.gov and Health Canada PRCI vs. what will be made public in CTIS.	Cross-functional task force should consider all registries and confirm a consistent approach



Leading Disclosure & Transparency teams are embracing “the new world” of Disclosure

Align Internal and Regulatory Policy Expectations

Gain economies of scale by implementing consistent processes to support regulatory disclosure and voluntary sharing policies

Use quantitative methodology to protect your risk, maximize data utility and meet regulator expectations

Implement Repeatable Processes

Global checklist

Local execution

Continuous improvement through documented procedures and retrospective reviews

Implement Future Proofed Technology

Support for regulator specific requirements

Must be fit-for-purpose

Flexible: Ability to manage in-house or via a reliable outsourced provider

Up Your Game: Make Transparency into a Strategic Advantage

Go beyond the minimum. Is meeting the regulator expectation enough?

Improve brand image and trial recruitment by implementing an industry leading disclosure policy

Do what you say!



End