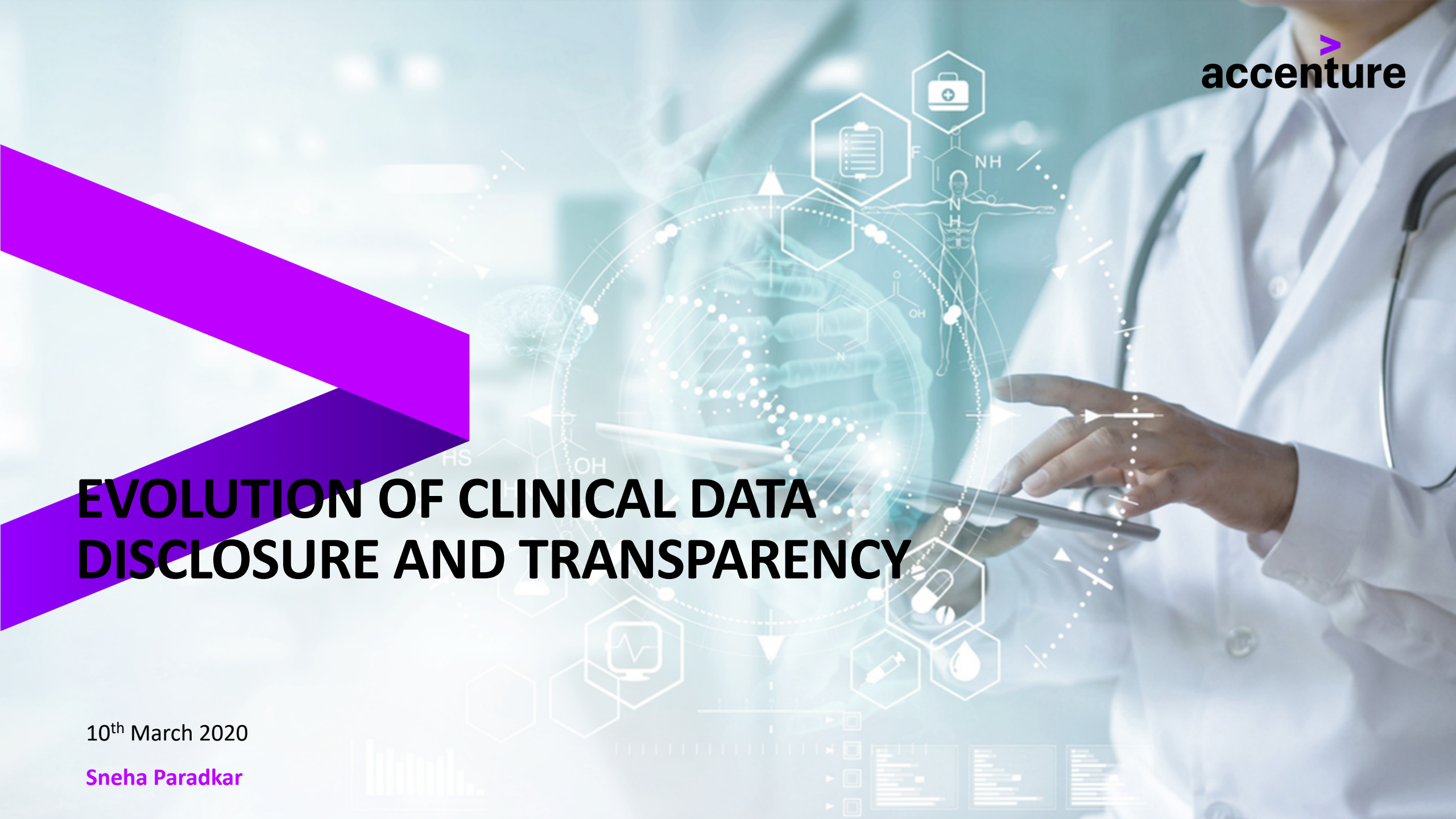


The background features a blurred image of a doctor in a white coat with a stethoscope, holding a tablet. Overlaid on this are various medical and technological icons: a DNA helix, a human silhouette with internal organs, chemical structures, a brain, a heart rate monitor, a syringe, and a water drop. A large, vibrant purple chevron graphic points from the left towards the center text.

EVOLUTION OF CLINICAL DATA DISCLOSURE AND TRANSPARENCY

10th March 2020

Sneha Paradkar

AGENDA



Registries used for Clinical Data Disclosure



Milestones related to NIH and EUDRACT databases



Impact of BREXIT on EUDRACT postings



Plain Language Summary Tables



Impact of CDDT Evolution

WHY CLINICAL DATA DISCLOSURE?

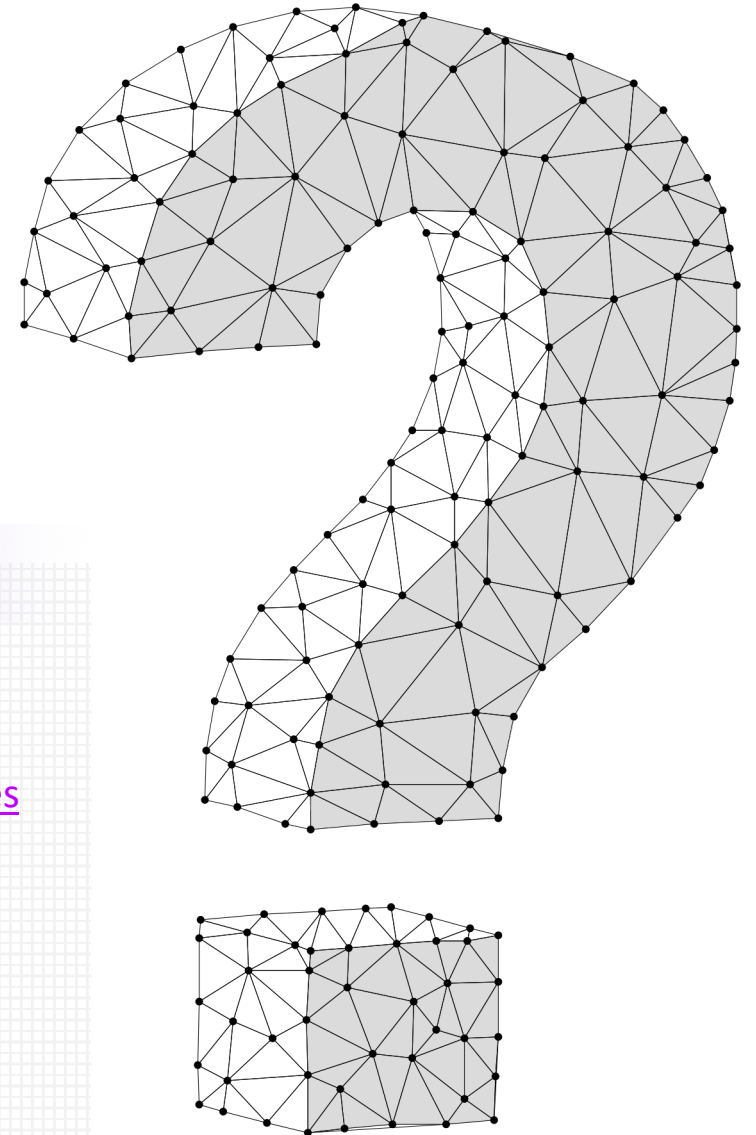
- Evidence-based decisions in medicine.
- Legal obligations and compliance factors.
- Global cost reduction of drug development.



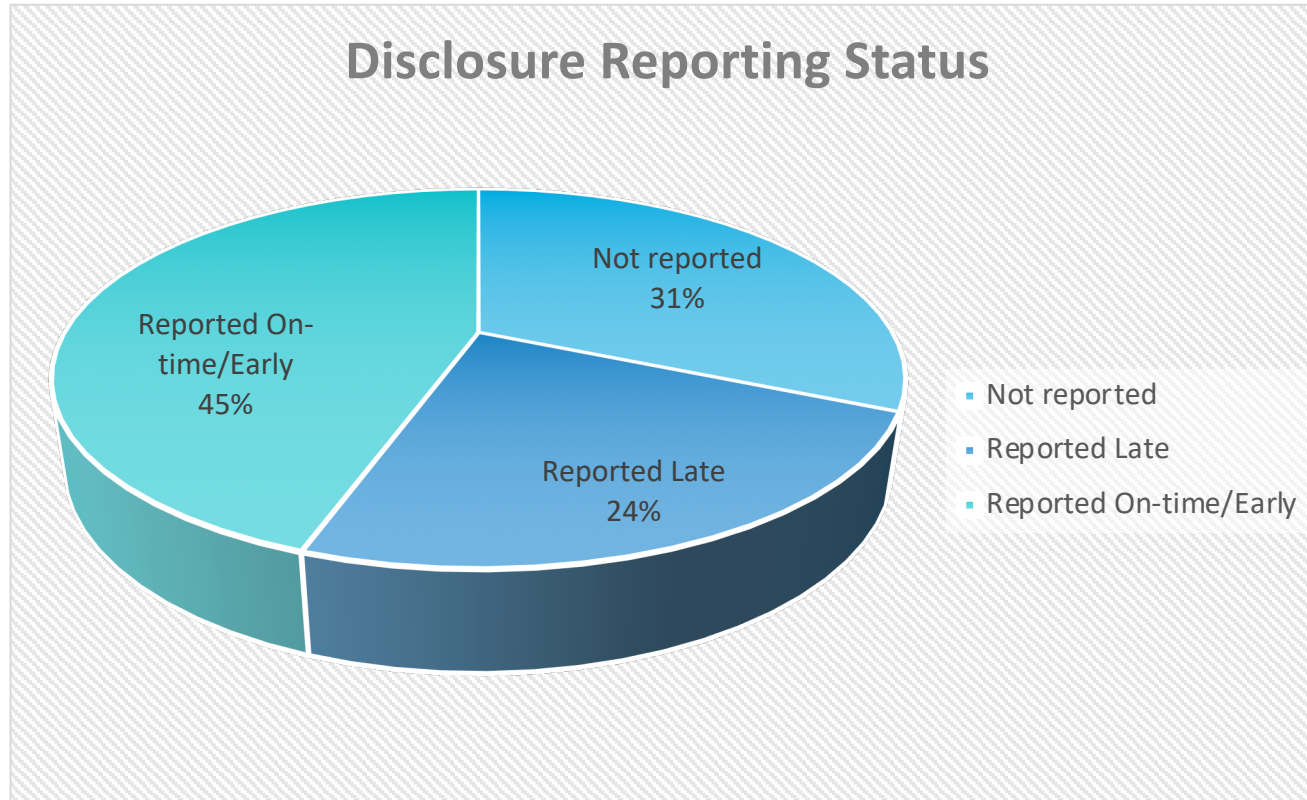
Registries for Clinical Data Disclosure

[ClinicalTrials.gov](https://clinicaltrials.gov) - Registry of privately and publicly funded clinical studies conducted around the world, maintained by the [National Library of Medicine](#) at the [National Institutes of Health](#) in collaboration with US FDA

[EudraCT](#) - European [clinical trials database](#) of all [clinical trials](#) of investigational medicinal products with at least one site in the [European Union](#) commencing 1 May 2004 or later.

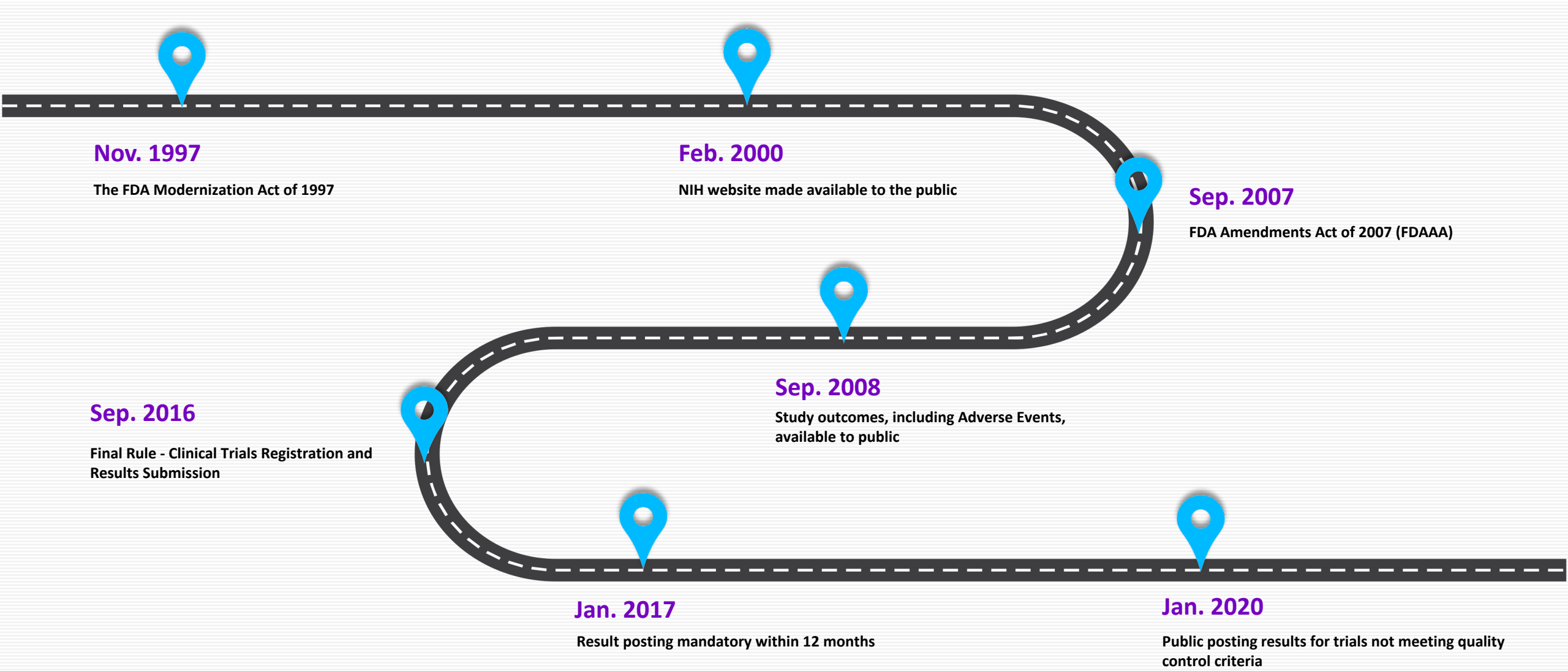


STATISTICS OF RESULTS DISCLOSURE

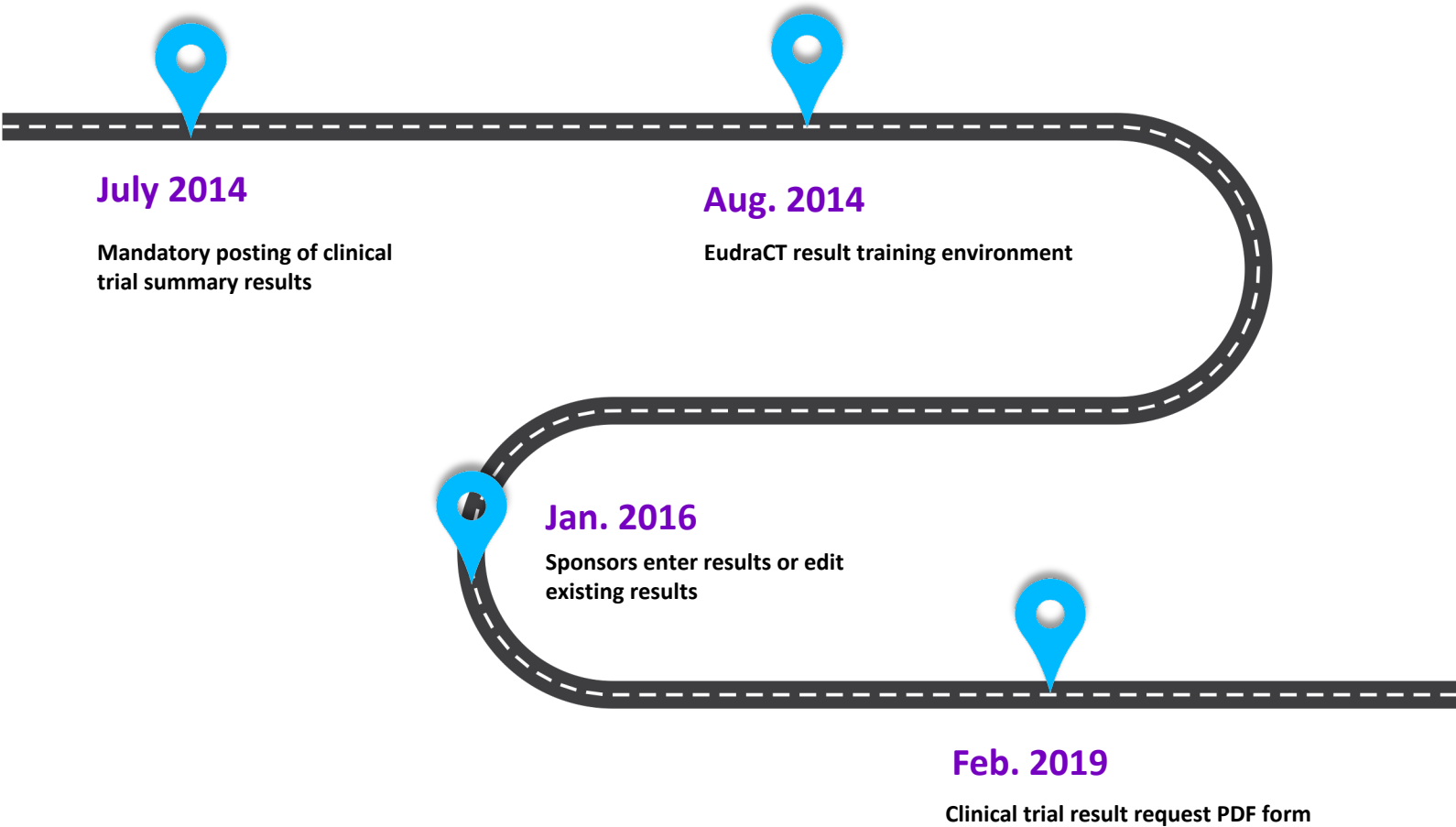


In more than **4700** clinical trials examined by a *Study*, **45%** trials had their results reported early or on time to ClinicalTrials.gov.

MAJOR MILESTONES - CLINICALTRIALS.GOV



MAJOR MILESTONES – EUDRACT AND BREXIT IMPACT



- No longer submission of Protocol-related information
- Exception - Trial is part of an agreed Pediatric Investigation Plan.
- Results of completed studies conducted in UK before withdrawal date to be submitted.

PLAIN LANGUAGE SUMMARIES

- Synopsis of the trial analysis in a simple language
- EU Clinical Trials Regulation 536/2014 (EU CTR Article 37)
- For all Phase I through IV interventional trials
- Submit to the EU database as per regulatory timelines
- Easy to read and understand

- Technical terms in simple language
- Unambiguous information
- No assumption of trial data
- No promotional content to be included
- Numeric data to be easily understandable



IMPACT OF CDDT EVOLUTION



CHALLENGES

- Collaborations/Joint ventures
- Data of Legacy studies
- Non-standard data format
- Regulatory Compliance
- Financial loss
- Innovation
- Automation



TIPS TO OVERCOME HURDLES

- Troubleshooting issues
- Effective Communication
- On-time alerts
- Collaboration
- Discuss and document discrepancies

CASE STUDY

PROBLEM



Raw datasets needed to be mapped to SDTM, annotated CRF was unavailable, legacy study hence none from client study team was available to confirm the derivations. Timeline for submission was critical since it was a Pediatric study.

SOLUTION



Programmed the raw datasets into SDTM format, coordinated with various stakeholders like study team, medical coding team, statisticians and medical writers on time, provided status updates to CDDT team. Generated the adverse event reports and XML and provided to the CDDT Medical writers on time with quality.

IMPACT



Data was accurately reported on time, client met regulatory timelines and did not have to pay any penalty.

REFERENCES

<https://eudract.ema.europa.eu/>

<https://clinicaltrials.gov/>

<https://www.who.int/ictrp/results/jointstatement/en/>

<https://www.synchrogenix.com/brexit-impact-on-eudract/>

<https://www.sciencemag.org/news/2020/01/fda-and-nih-let-clinical-trial-sponsors-keep-results-secret-and-break-law>

