

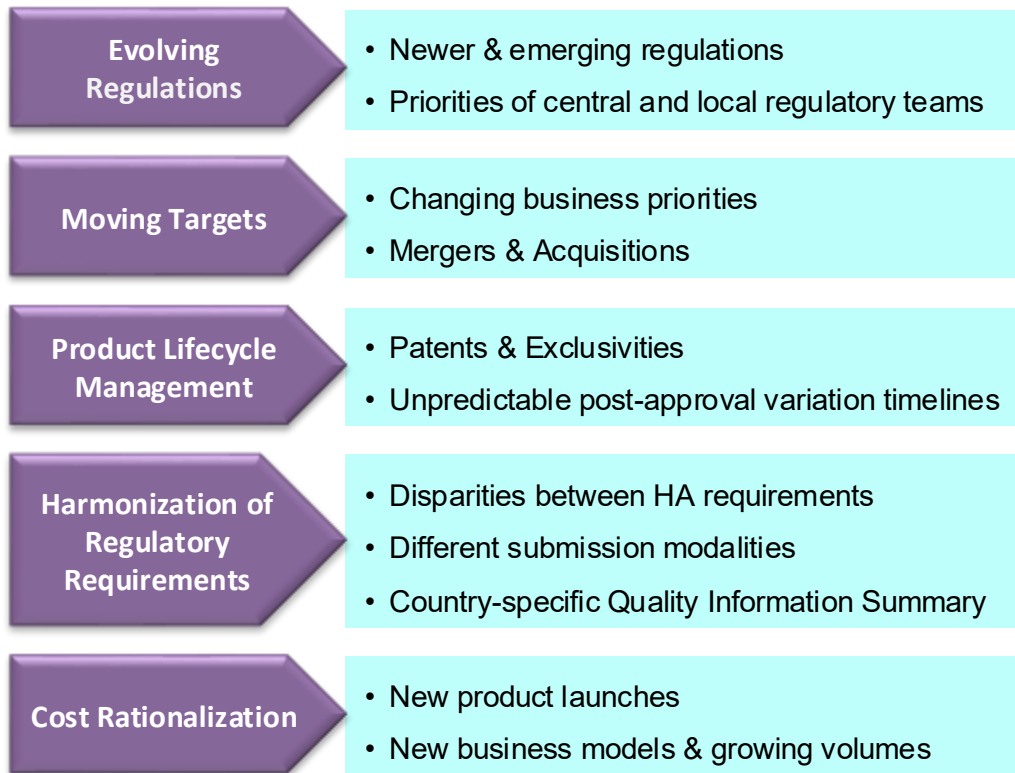
Single Day Event

Leveraging Technology in Regulatory Submissions
– An Evolving Landscape

Dr. Rajneesh Vats,
Tata Consultancy Services, Mumbai



Industry Pain Points & Trends



Business Trends

eCTD 4.0

IDMP

FHIR

HL7

Regulatory
Intelligence

TMAP/
KASA

Technology Trends

AI/ GenAI

Cloud/
Data lake

Data
Analytics

AgenticAI

RWE/
RWD

Blockchain



Some Statistics to Ponder On!

Technology Adoption in Pharmaceutical Industry – Global Top 20 Sponsors** Snapshot

2023-2024

94% CDER Submissions
77% CBER Submissions

Strong evidence that Large Sponsors are fully digital for US submissions¹

FDA eCTD v4.0 & EMA eCTD v3.2 adoption

Major Sponsors are updating their systems/ process accordingly^{2,3}

AI/ GenAI Adoption

100% of surveyed Pharma/ MedTech leaders experimenting with GenAI⁴; **32%** scaling⁵

70% say AI is immediate priority (**85%** in Big Pharma)⁶

Cloud & Data Platforms

~34% of firms use public cloud in all areas, **51%** in some⁷

Life sciences cloud market **CAGR >21%** through 2030⁸

Real World Data & Evidence

FDA Sentinel System: Massive data backbone of **500.1 million** unique patient identifiers⁹

EMA DARWIN EU®: **70+** RWD studies 2024; plan to exceed **140** studies/ year from 2025¹⁰

Digital Manufacturing/ Pharma 4.0

58.1% in advanced Pharma 4.0 stage; “not started” down from 31.2% (2020) to **15.1%** (2024)¹¹

Benefits: fewer deviations (**54.6%**), higher yield (**46.2%**)¹¹

Investment Momentum

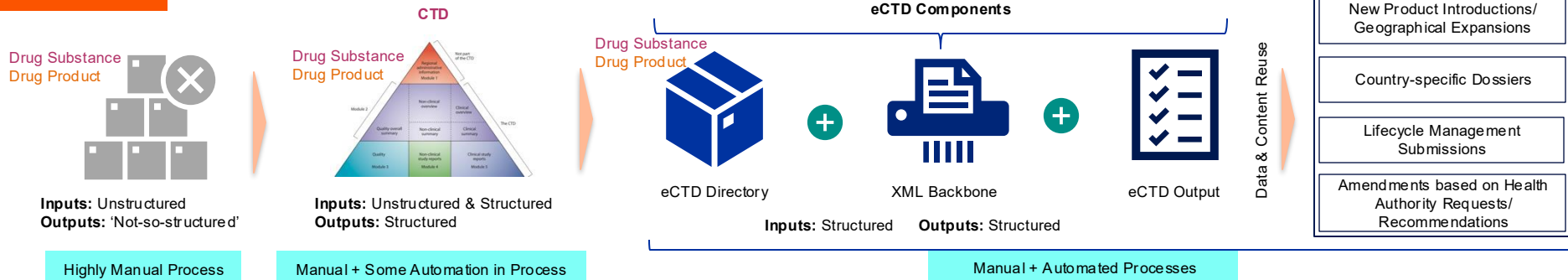
93% of life sciences tech leaders plan to increase data/ digital/ AI spend in 2025¹²

* Sponsors Considered: Pfizer, Johnson & Johnson, AbbVie, Novartis, Roche, Merck & Co., Bristol Meyer Squibb, Sanofi, AstraZeneca, GSK, Eli Lilly, Takeda, Novo Nordisk, Boehringer Ingelheim, Bayer, Amgen, Gilead, Otsuka, Daiichi Sankyo and Biogen.

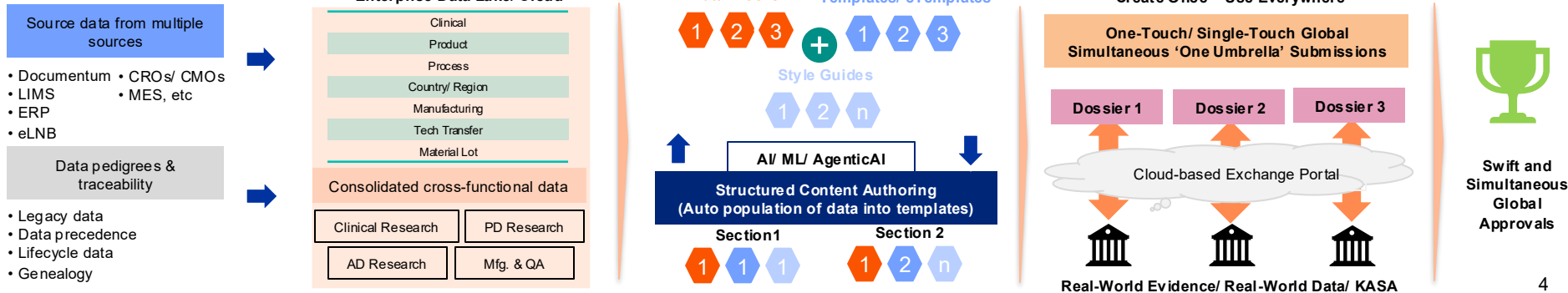


How to Get Going & Get There...

Evolution



Aspiration





Some Recommendations & Key Takeaways



Embrace an Enterprise Data Lake (EDL)/ Cloud for faster realizations of regulatory objectives



Prioritize metadata and taxonomy in RIM to speed future publishing and swifter submissions



Engage regulators early (pre-IND/ Scientific Advice) on novel data sources and automations (RWE, AI)



Unified submissions to discrete Health Authorities together is not a myth!

1. <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/data-standards-program-strategic-plan-and-board>
2. <https://www.federalregister.gov/documents/2024/09/16/2024-20897/electronic-common-technical-document-data-standards-center-for-drug-evaluation-and-research-and>
3. <https://esubmission.ema.europa.eu/ectd/>
4. <https://www.mckinsey.com/industries/life-sciences/our-insights/scaling-gen-ai-in-the-life-sciences-industry>
5. <https://www.fiercepharma.com/marketing/ai-tech-immediate-priority-most-big-pharmas-many-plan-open-their-pockets-further-ai>
6. <https://www.mckinsey.com/capabilities/quantumblack/our-insights/the-state-of-ai-2024>
7. <https://www.pwc.com/us/en/tech-effect/cloud/cloud-ai-business-survey.html>
8. <https://www.mordorintelligence.com/industry-reports/cloud-computing-market>
9. <https://www.sentinelinitiative.org/about/key-database-statistics#:~:text=The%20Sentinel%20Distributed%20Database%20has,more%20than%20one%20patient%20identifier.>
10. <https://www.ema.europa.eu/en/news/darwin-eur-continues-expanding-its-capacity-deliver-real-world-data-studies>
11. <https://ispe.org/pharmaceutical-engineering/september-october-2024/ispe-global-pharmaceutical-innovation-survey>
12. <https://www.zs.com/insights/2025-survey-data-digital-ai>

Thank You!



**The Global Healthcare
Data Science Community**

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