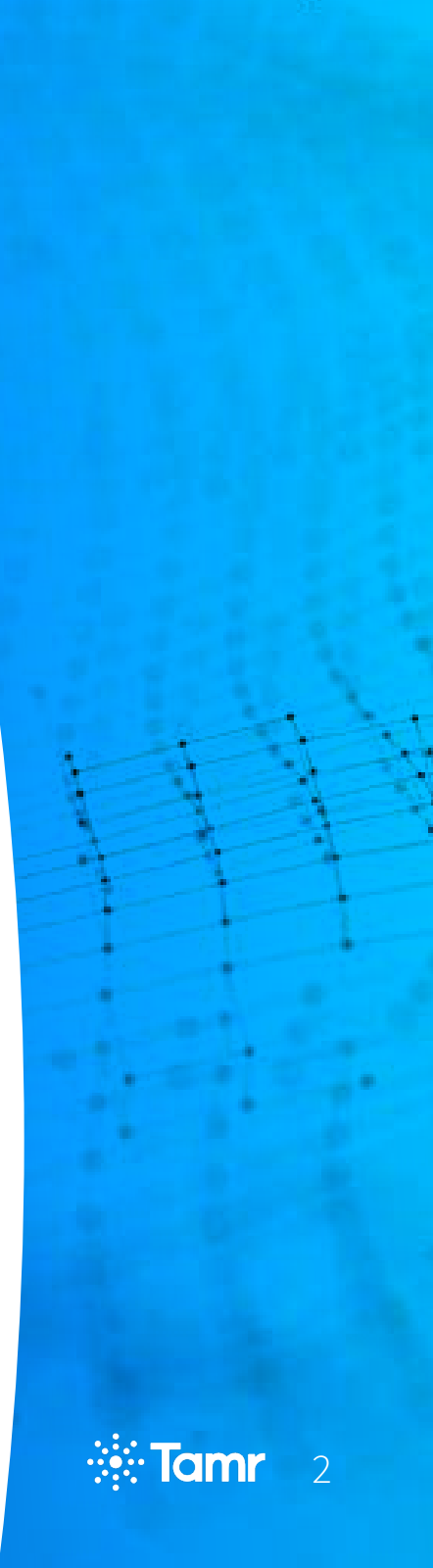
7 Steps for Boosting R&D Outcomes with Historical Clinical Trial Data

Tamr

7 Steps

1. Get organizational approval for secondary use of clinical trials data
2. Determine clinical and non-clinical use cases for clinical trials data
3. Obtain read access to completed clinical trials data
4. Take an agile, DataOps approach to clinical trials mastering
5. Enrich clinical trials with real world data
6. Understand linkage of clinical trials data to other data sources
7. Develop advanced analytics skills of the team



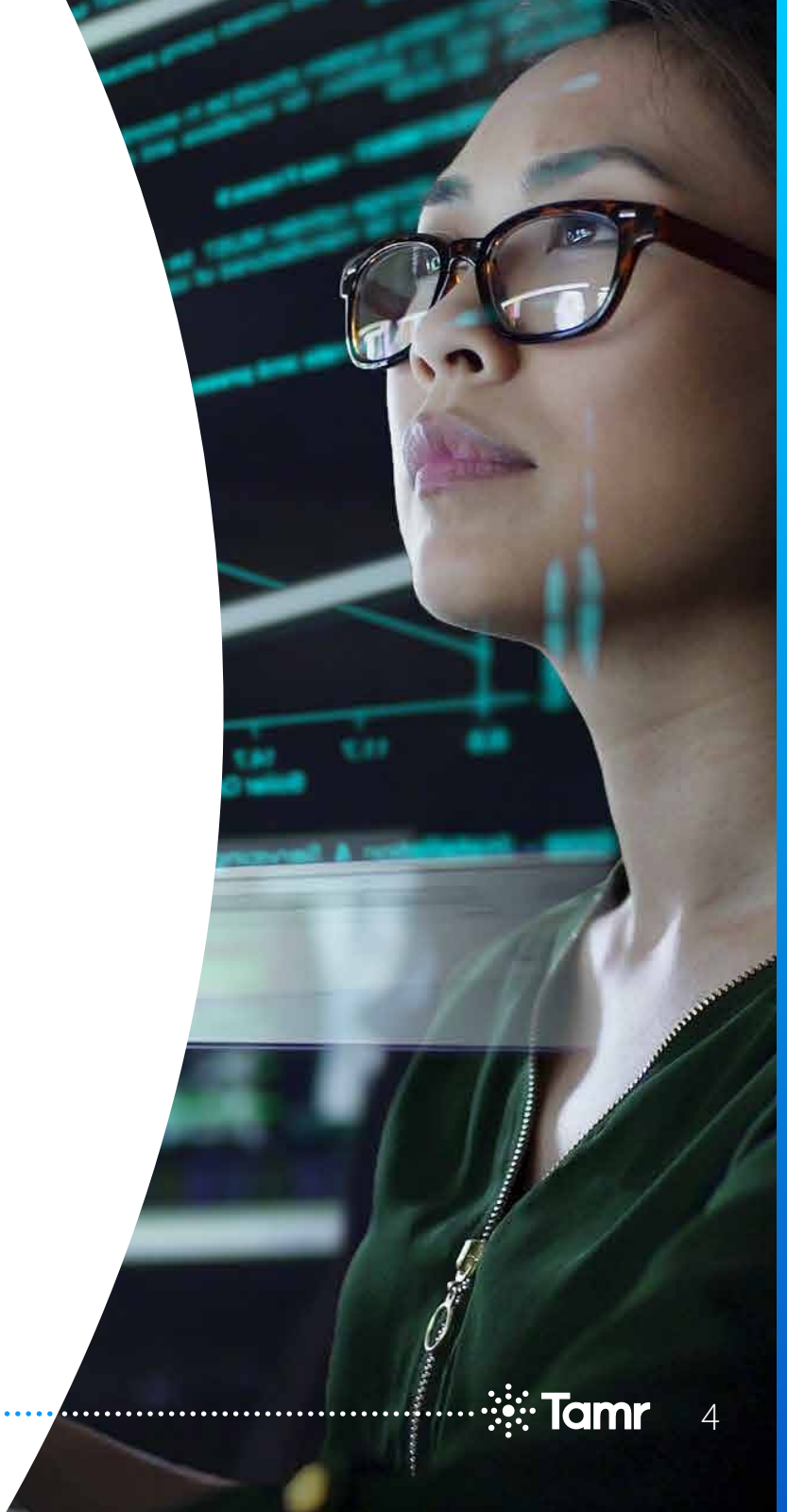
Pharmaceutical companies are under immense pressure to research, develop, and bring to market new drugs and therapies in a way that's fast and cost efficient. However, at the moment, it can cost up to $2.6bn and take 14 years to move a drug from **"bench to bedside."**

Obviously this cost is too high, and at present cannot sustain future drug development. So, like other industries, pharma companies are looking for data to help drive greater efficiency, improve performance and reliability, and crucially, unlock new insights. One area in pharma organizations that has a wealth of latent data potential are historical clinical trials.

Until recently clinical trial data was single use. The explicit purpose and goal was to determine the characteristics and potential effectiveness of a particular medicine. And once those characteristics were determined, the new medicine would be either filed and move on to become a new commercial product, or it would fail to meet expectations and the program was discontinued. Today with advances in core technologies (cloud computing, machine learning, and AI) pharma companies can rationalize their portfolio of historical clinical trials and reuse them to uncover new discoveries and improve the operations and

effectiveness of future clinical trials. Giving this data a "second life" can net huge savings for organizations—especially for research and development (R&D).

To effectively make this data into a new asset, pharmaceutical companies need strategies for rationalizing and leveraging their historical clinical data. Here are seven steps to begin a robust program for rationalizing historical clinical trial data and creating a valuable data repository for R&D teams:



1

Get organizational approval for secondary use of clinical trials data

Fair warning: it's no small task to get access to a portfolio of historical clinical trial data for secondary use. Changing the way your organization thinks about and uses its historical clinical trial data is often a dramatic shift to how things are done. Changes might be met with apprehension or skepticism by others in your organization. In order to set yourself up for success make sure you have buy-in at the highest levels in your organization. CEOs need to believe that the organization's historical clinical data is a strategic asset that will deliver value - and not that it is a pet project or waste of time.

One area that gets a lot of scrutiny from executives is informed consent agreements and the language authorizing secondary use. Over the last few years many organizations have adapted language in patient consent forms to account for this.

However, using historical trials will still require input from legal teams to assess language and determine how the data can be leveraged. Teams need to be purposeful about how far back they go for their analysis.

Sometimes, as organizations assess risk with regards to privacy laws and treating data for anonymization, the “safe” decision might be to lock down data. But this is not without its own risk. If scientists can’t get the data they need internally, often they will purchase external and third-party trials data. This practice opens a whole new set of risks. Having these risk remediation discussions about trade-offs are why executive buy-in to the program is critical.

2

Determine clinical and non-clinical use cases for clinical trials data

When given the option, most people will say they want access to more data. Despite their good intentions, asking for and receiving more data usually results in a negative outcome: slowing the time to discovery and development of new therapies.

In order to push back on the idea that “more data is better,” ground conversations about using clinical trial data by asking a few important questions. How will you use the data? What new questions will you ask? What decisions will you make and what will you do differently?

It’s critical that all stakeholders—scientists and the business—participate in these early conversations because they will be the ones who ultimately own the project from here on out. Helping these groups understand what data is available, and then providing guardrails around its usage, will result in better or faster decision making and not just continue to add more layers onto what's already happening.

3

Obtain read access to completed clinical trials data

Let's state the obvious: nothing can be done until you have access to the clinical trial data you need. But getting access to data is a common point of failure when trying to change how clinical trial data is used, and again, reinforces why organizational approval (see tip #1) is so vital.

Typically, the team that executed the original trial owns the data and it's up to them to choose who can access it and for what purpose. If a scientist is interested in evaluating data from a past clinical trial, they have to present their case to this original group and wait for their determination about whether or not they will share the data. With one group acting as gatekeeper, it prevents

the entire organization from benefiting from an integrated rationalized view of an entire portfolio of clinical trial data.

By getting executive approval and read access to every clinical trial in a portfolio, you are freed from having to work in this case-by-case pattern and work faster and free more data for use.

4

Take an agile, DataOps approach to clinical trials mastering

Rationalizing clinical trial data is not a one-off project. Once you have access to the trial data you need to make sure that data stays current. In the case of clinical trials that means it is in CDISC format. The issue is standards like CDISC are always changing. In order to maintain a portfolio of clinical trial data (with potentially thousands of trials and billions of unique data points) you need an operational framework that ensures data accuracy and availability at scale. Enter DataOps.

DataOps is an agile framework for managing people, process, and technology in order to help data teams accelerate the analytic outcomes of data for the enterprise. Using DataOps helps mitigate problems like schema drift, better leverage technologies that allow for a high degree of automation (AI and machine learning (ML)) to keep data clean and current, and ultimately ensure that the best data is available to people who need it across the organization.

5

Enrich clinical trials with real world data

Once pharma organizations have created a comprehensive clinical trials data repository and have effectively designed data workflows and leveraged ML to accelerate harmonization, these same DataOps principles will accelerate the ability to integrate real world data (RWD) and other third-party data (e.g., EHRs) into the data repository.

As a next phase of the clinical trials data repository, converting harmonized CDISC standard data into the OMOP standard will lay the foundation for effective enrichment with real world data sources. ML is an effective mechanism for mapping and converting standards at large scale, but requires data experts to provide feedback on data remediation needs.

As governing bodies like the FDA have improved frameworks for leveraging RWD and real world evidence (RWE) in new product and drug submissions, pharma companies are better positioned to leverage RWD and RWE as a competitive advantage in clinical trials research as well as new product and drug development.

6

Understand linkage of clinical trials data to other data sources

Leading pharma companies that have invested in leveraging their historical clinical trials data as an asset have developed the data strategies that are foundational to connecting additional external data sources such as EHRs and genomics data sources (e.g., biobank).

Connecting external data and understanding linkage to clinical trials data drives the transformative insights that boost R&D outcomes. What does comparative analysis of characteristics and phenotypes within the clinical trials data show? How does that compare to a much larger patient population in the real world data? And how does that link to genetic variance in the UK biobank data?

“Connecting the dots” across these highly variable—and valuable—data sources will empower R&D teams to uncover new insights more quickly.

7

Develop advanced analytics skills of the team

Again, like the problem of too much data, a lack of analytic focus and expertise hurts progress.

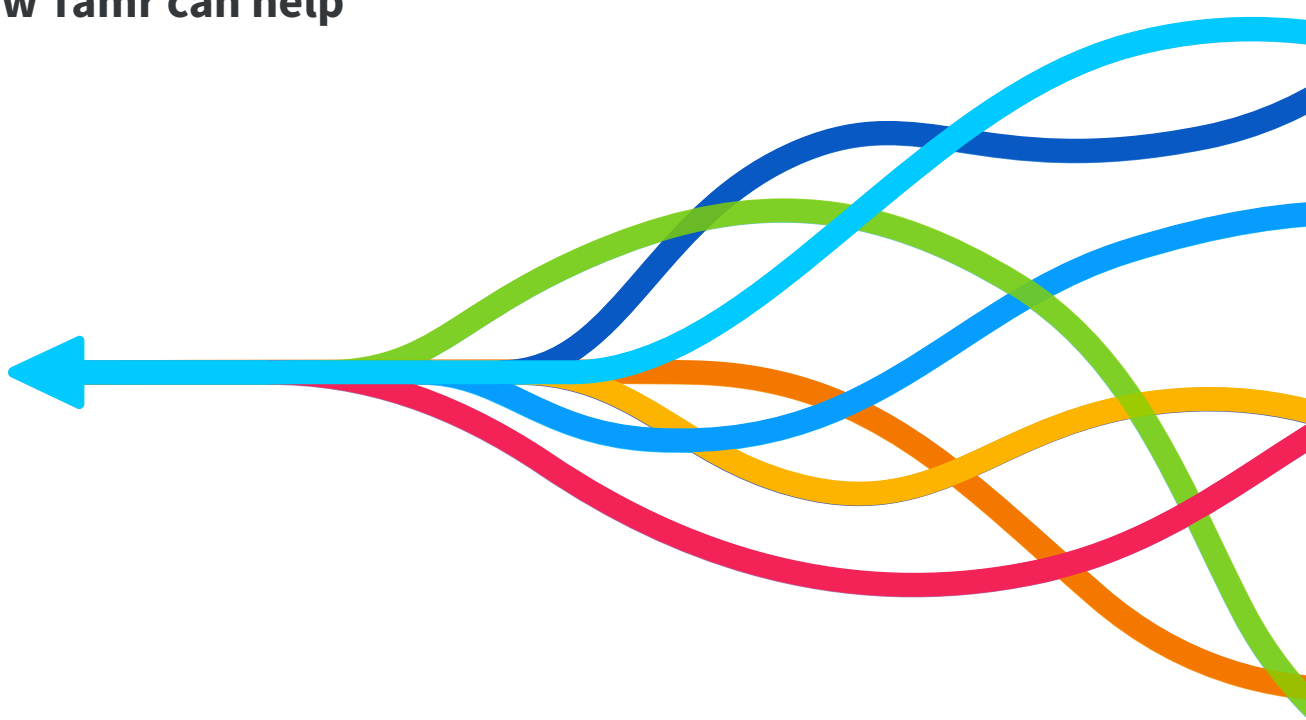
Pharmaceutical organizations should build or internally develop a dedicated team of highly skilled analytics pros. The team should become their organization's center of excellence for analytic skills and drive the consumption of the rationalized data into AI and machine learning models that better inform decision making throughout the company.

Next Steps

Tamr is helping Global pharmaceutical companies maximize their historical clinical trials data and bring new drugs to market faster.

Start a conversation about how Tamr can help your organization.

Talk to Tamr



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About Us

Tamr is the leading data mastering company to accelerate data-driven business outcomes. Industry leaders like: Toyota, Societe Generale, GE, and Thomson Reuters trust Tamr to manage their enterprise data as an asset. Tamr's unique approach of using human-guided machine learning algorithms to accelerate data mastering projects lets the world's largest organizations enhance their data operations, rapidly activate latent data, and increase the velocity of business outcomes through data-driven insights. With a cofounding team led by Andy Palmer (founding CEO of Vertica) and Mike Stonebraker (Turing Award winner) and backed by investors including NEA and Google Ventures, Tamr is transforming how companies get value from their data.

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