Paper PD03

Big Pharma acquires Biotech – perceptions from the clinical data scientists' point of view

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ABSTRACT

Novo Nordisk has a strategy to expand its presence across a range of new indications closely linked to Novo Nordisk's core business. A consequence of this from a clinical data scientist perspective is the evaluation and integration of acquired clinical trial data and documentation. In other cases, partnering with new colleagues from different cultures are required.

This paper we will focus on three aspects of this:

1. evaluating and incorporating the clinical trial data into the acquiring company.
2. the thoughts and reflections from the acquired company's perspective on the acquisition.
3. a joint view on the integration of a 300-employee biotech company into a major healthcare company like Novo Nordisk with over 55,000 employees[1].

The paper is a high-level look at the world of mergers and acquisitions within the pharmaceutical industry, from the desk of clinical data scientists.

INTRODUCTION

The acquisition of Dicerna Pharmaceuticals by Novo Nordisk was the 5th biggest Mergers and Acquisitions (M&A) Biopharma deal, in monetary value, in 2021[2]. This investment supports Novo Nordisk's strategy of developing and applying a broad range of technology platforms across all Novo Nordisk therapeutic areas.

In this paper we will share some of the elements and considerations going into our evaluation of the acquired company's biostatistical deliverables. We will also be sharing some of the perceptions as seen from the acquired company's side, considering the differences in culture, leadership, management style, unfamiliar systems, and procedures, etc. and how to cope with these changes and periods of turmoil. In the final part of the paper, we will share some of our learnings on personal as well as organizational levels. In our analysis of coping with changes during a M&A we will be using the Kübler-Ross Change Curve to explain and understand the required steps for a successful integration.

EVALUATING THE CLINICAL TRIAL DATA AS AN ACQUIRING COMPANY

The first thoughts one might have once a Biotech's compound has been acquired and the acquiring company (Novo Nordisk for instance) should insource running trials into our current portfolio of trials, is:

> *What is the quality of the electronic data and associated documentations including program?*
>
> *Can we navigate within their trial data and find what is relevant to address all potentially questions we might be faced with by internal as well as externals?*

When we are analysing this, we need to look at it from an agency perspective. The agency is the receivers of electronic data on submissions, and their task is exactly to navigate within the submitted trial data to answer all the questions regulators might have.

In the following sections we give our view on evaluation of the clinical study data package(s). We strive to optimize the evaluation approach and give direction to find the right balance in involvement and requests for changes from sponsor to the acquired company (or contract research organization, CRO, if it has been outsourced) - always having submission requirements in mind when performing the evaluation.

ESTABLISHING THE RIGHT COLLABORATION

The main key to success - in general aspects - is mutually collaboration between the acquired and acquiring companies – in our case between Dicerna and Novo Nordisk. Especially the sponsor should focus at being a proactive and engaging partner. Irrespective of the setup, it is important early in the process to discuss and address the following:

A. How the collaboration should work – what is expected from both parts?
B. How is the communication maintained?
C. Clear responsibility split for
    a. specific deliverables, what by when and whom
    b. activities – who does what?

As inspiration, overviews of deliverables and tasks in Appendix tables 1 and 2 are a good initial checklist for the kick-off meetings with the acquired company/CRO and will facilitate a common vocabulary of expected deliverables in the company or CROs data package

PLANNING AND EVALUATE THE TRIAL DATA

When planning an evaluation of trial data of an acquired company/CRO, assessment of future use of the trial should be considered. Such as trial type, complexity, future use of data going forward, type of deliverables, previous experience of deliverables from the acquired company/CRO etc. That defines the current scope of the trials purpose and will make the evaluation easier especially if issues occur.

There are 3 items that recurrently needs to be worked on: I) The risk profile for trials in scope; II) A communication platform for issues and data exchanges; and III) items to look for and checking of.

I. RISK PROFILE

A risk profile should be discussed and agreed between the clinical data scientists and project management. This will ensure an aligned direction of the evaluation, agreement of the quality level and where to be risk willing, and the risk profile should be used actively. One way to use it could be to identify what is most important endpoints and potential a few extra cross checks based on quality of the received deliverables in Appendix table 2.

It should be considered if a discovered issue is important enough to be corrected by the company/CRO (or by sponsor in case the collaboration is over) or if it is sufficient to describe the issue in an issue tracker to document the finding.

II. ISSUE TRACKER AND EXCHANGE OF DATA PACKAGE

It is recommended to establish a communication platform for issue tracking, see Figure 1, as this will ensure efficient project management with access to answers and information and maintain a tracking of the history of issues, solutions, and delivery milestones. This makes creating reports, monitoring issues, and sharing information far easier and can also turn out to be beneficial at a later point in time to document decisions taken.

Issue No.	Source	Review initals	Type	Sub-type	Action	Issue text	Date Raised	Status	Response details	Response date	Response by
Example	Output	Novo Nordisk	Tabels	tae.sas	Query	Please include footnote xxx in table 8.2.11	1-Dec-2023	On-Hold	Yes the footnote will be included to match with deliverable	25-Dec-2023	Resolved

Figure 1 Example of issue tracker maintained in Excel. With Issue no, how found the issue, a description of the issue, where the issue is in the data package and resolution details with date and initials.

Preferably the company/CRO should provide the portal for the data transfer i.e., SharePoint, BOX.com etc. No data or documents should be exchanged via email.

It is a good idea to create a transfer log file as there can be many iterations of transfers and having an overview and being able to identify each will be significant both in the period of evaluation and for future reference.

III. WHAT TO LOOK FOR AND HOW TO DO THE REVIEW

It cannot be expected that the received data packages have been created with the same standard as sponsor deliverables. Good programming practice (GPP) should be evaluated and can be a good proxy indicator for the quality of the data package i.e., if most programs have poor GPP this could indicate that a thorough evaluation is needed.

A timestamp check of datasets and relevant files can give an important overview of the dataset package consistency and quality, ensuring e.g., that the ADaM has run before the Tables Listings and Figures (TLF) output.

In the Appendix you find a list of items that should be evaluated, listed in the issue tracker and judge within the risk-framework. It also includes appendix table 1 and 2 in a printable format in order not to forget potentially relevant items.

SUBMISSION READINESS

In our experience we would recommend to upfront create a M5 folder structure[3] as seen in Figure 2 in connection with the evaluation a folder structure like described in the Food and Drug Administration (FDA) study data technical conformance guide. Placing all submission files in their respective folders, ensuring all files intended for submission are available and accounted for, and thus enabling a test on all links from the define file.

CONCLUDING ON THE SPONSOR EVALUATION

It is important to document the evaluation and decisions taken to each issue found and track these in the issue tracker with a conclusion. The overall conclusion of the evaluation should be presented to project management. As the submission format is most likely not aligned with the sponsor format, it is important to be transparent and get this endorsed by project management and regulatory affairs.

The statistical conclusions are most likely already presented in a clinical study report, a result meeting or can be included in the overall conclusion meeting minutes.

Critical issues from the issue tracker, which are deemed necessary to have corrected, must be brought forward and resolved by the company (or CRO) in agreement with project management. If a sponsor is to resolve the issues it should be considered how to do this, to ensure traceability between existing deliverables from the company or CRO and the corrected programs and data.

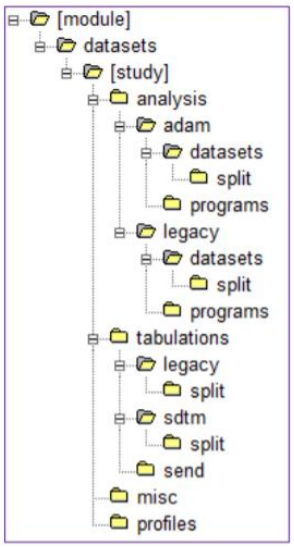

Figure 2 FDA SDTCG v4.1, M5 folder structure for study datasets

THE ACQUIRED COMPANY'S PERSPECTIVE ON THE ACQUISITION

There is a difference between making the acquisition itself and making it successful. Generally, there are two ways to make it work.

I. Emphasize the strategic fit between the acquiring company and the acquired company and ensure that the acquired company can conform to the acquiring company's strategy all-round.

II. Find an organizational fit between the two companies by matching administrative systems, corporate cultures, or demographic characteristics.

Whichever process is used, sufficiency and persistence in the strategic implementation are the keys to the acquisition's success.

FIRST PERIOD CHALLENGES AFTER AN ACQUISITION

Dicerna has identified the following divergent from Novo Nordisk that may take time to overcome

- Cultural differences
- Report Structure
- Standards and Procedure
- Roles and Responsibilities
- IT and Computer System
- Geographic location

CULTURAL DIFFERENCES

Novo Nordisk and Dicerna share multiple core values in working places: open and honest, ambitious, accountable, and treating everyone with respect. Despite those shared values, the acquired company (Dicerna) would inevitably experience feelings of inferiority compared to the acquiring company (Novo Nordisk). With any acquisition, there is the question of "what value will the acquired company bring to our business", and it's natural for employees of that acquired company to wonder if they are a part of that judgment. Given that, the acquiring company must be mindful of this when making integration decisions about retaining acquired employees who hope to be treated equally after assimilating into the Novo Nordisk family.

REPORT STRUCTURE

Additionally, Novo Nordisk's reporting structure, decision-making procedures, and other business processes are more robust and complex than Dicerna's. Novo Nordisk is typically structured so that decision is making is separated according to hierarchy levels; different geographical, therapy, and functional areas which naturally creates silos. Dicerna's integration into that model is mostly a new arm being added to the Novo Nordisk "family tree." This has the benefit of allowing ongoing Dicerna projects to have as few speed bumps as possible but also can instil a sense of isolation from the Novo Nordisk company. While no one solution will address all issues, it is essential to be mindful of how integration into the existing reporting structure will affect the new employees

STANDARDS AND PROCEDURE

Being a small biotech company and looking to reduce overhead and costs and streamline its businesses, Dicerna outsources almost all Biostatistics and Programming activity to CROs as its primary working model. Conversely, Novo Nordisk only outsources non-core services and resources. It has a meticulous and comprehensive development system and procedure for clinical data handling and reporting. This disparity necessitates that Dicerna staff need systematic training to know these standards, templates, operation guidance, and processes, Open communication is critical to identify these knowledge/practice gaps, and then both parties could jointly develop a working plan to help acquired side to address them.

ROLES AND RESPONSIBILITIES

Dicerna had around 300 employees when Novo Nordisk acquired it. It avoids multiple layers of management and headcount redundancy. The Dicerna employees in some departments play various roles and support a much more team-oriented, cross-functional, highly communicative organization. While there is similarity in roles and responsibilities within departments across the two companies however, the differences are expected. As an example, Statistical Programmer at Dicerna maintained ownership of SDTM datasets, including their creation and maintenance. Novo Nordisk, on the other hand, places that responsibility with their Data Management group. It is important to identify these gaps in roles and responsibilities and create plans to address them.

IT AND COMPUTER SYSTEM

Different companies will have their respective computer systems. While obvious, bridging the gap between the two during an acquisition is crucial. The most direct route is for the acquiring company to have the acquired company transition to its systems and phase out its existing systems, but, as with most things, this is easier said than done. During our integration, multiple issues have arisen that have added time and delays to the migration to Novo Nordisk's systems. One example directly results from the difference in ownership of SDTM files between our two companies. Permissions on the Novo Nordisk system rely on the assumption that Data Management will own SDTM activities, but when a company that places that ownership with Statistical Programming, like Dicerna, IT can suddenly find that those existing assumptions are now a hurdle. During an acquisition, it is not only crucial to try and identify where these issues might arise, but also to plan for unforeseen issues to arise and be flexible

GEOGRAPHIC LOCATION

Novo Nordisk is headquartered in Copenhagen, Denmark, with offices worldwide. There are 6 hours differences between Copenhagen and Boston, US, and 10.5 hours between Bangalore, India, another biometric hub, and Boston. It becomes a trick at best and impossible at worst to schedule an all-hands meeting at typical working times in each location. It is beneficial that the acquiring company could anticipate the geographic factors' influence on the business running model and has an initial resolution to leverage its impact.

REACTIONS FROM THE ACQUIRED EMPLOYEES

Job security was the most significant anxiety and concern during the M&A process for those employees in the acquired company, Dicerna. A lot of efforts, from Novo Nordisk, was put in being proactive in addressing these concerns by having different leadership from Novo Nordisk meets directly with Dicerna employees, having one-on-one discussions where they solicit feedback and being open and transparent about the Novo Nordisk goals and ambitions. Beyond job security, other challenges and worries existed, such as asking for direction, the pace of integration activities, and having to complete work related to ongoing trials on top of acquisition-related activities.

The Greater Boston Area is also a known "hot spot" for biomedical research. In fact, more than 1000 biotechnology companies within the Greater Boston Area create a job market that favours employees seeking new opportunities, which can increase the possibility of turnover during a merger or acquisition. Dicerna was not immune from that. From the biometrics perspective, while turnover is expected, there is a lack of a plan to address it when it occurs. The acquiring and acquired companies must have contingency plans for both expected and unexpected loss of headcount.

CONCLUSION OF THE ACQUIRED COMPANY

The acquisition of Dicerna by Novo Nordisk is still a work in progress but, and a year in, it is helpful to reflect on what has worked well, what has not, and, most importantly, what we can learn. Dicerna of today no longer functions as one complete unit, the organizational structure has a substantial change as it become integrated with the acquiring company's culture. Employees have faced challenges including coping with changes in culture, new leadership, management styles, unfamiliar operation systems and procedures, etc. This turmoil is felt across every level of the Dicerna organization. Naturally, some employees decided not to be part of the new company and left for a variety of reasons. However, most of the biostatisticians and programmers stayed on, looking for and expecting new options for career growth and opportunity in Novo Nordisk. The acquired employee engagement and retention are important indicators of the success of an acquisition. Surveys, exit interviews, and turnover rates can provide valuable insights into employee morale and satisfaction.

M&A OF PHARMA AND BIOTECH COMPANIES

The Boston/Cambridge area has long been at the forefront of biopharma research, playing host to some of the most renowned research institutes, including Harvard University, MIT, and Massachusetts General Hospital. This region enjoys a vaulted status, and the life science industry employs 106,704 with an average wage of $201,549 for a total of $21.5 billion in Massachusetts-based salaries, according to the Massachusetts Biotechnology Council (MassBio) 2022 industry snapshot[4].

A successful M&A can only be achieved through a successful integration which ties closely together with the people and organisations within the two companies. A widely accepted model for understanding the change management it brings, is the adopted Kübler-Ross Change Curve[5]. It proposes a good perspective and forecast in the potential behaviour of the people affected by the acquisition, and by leaning to this model, one might cope better with the changes by knowing what they need to go through.

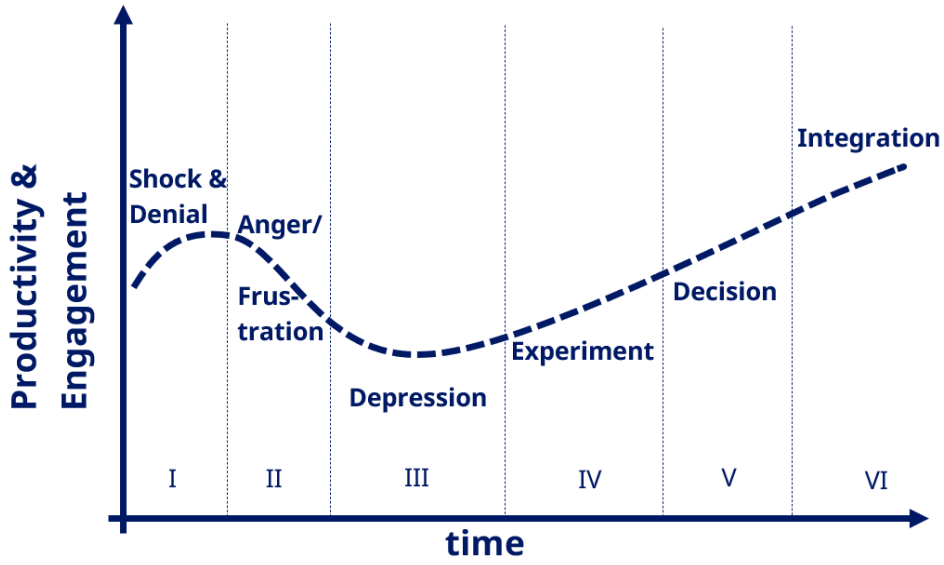

Figure 3 The Kübler-Ross Change Model, adaped to change mangement induced by a disruption such as a M&A for instance.

Obvious, the **shock** for the individual is biggest for the "small fish" at Dicerna rather than for the "big pharma" employee, at Novo Nordisk. However, both parties need to be considered, since it will affect them both. People might resist in the engagement since they even may **deny** the fact (mostly by the acquired employees) or don't expect it will affect them (more likely amongst the acquiring employees).

When this is realized, and the new situation is accepted it may lead to **anger** or **frustrations** resulting in a decline in productivity and engagement.

If the frustration are not controlled, it may potentially lead to a **depression**, where the engagement meets its lowest point. At this point a cofound integration plan is key to bend the curve, avoiding the team members to last in this phase for a long time. A collaborative approach of creating support systems among team members and employees can help them to help themselves.

With a new resolve, the person begins to engage with their situation. They shift from a more emotional response to a more rational and realistic one. They begin to **experiment** with ways to cope with the new situation, such as working with different IT-systems, standard operating procedures, co-workers etc.

Having experimented with ways to cope, the person arrives at a **decision** on how they will move forward and take control themself. They shift into 'action mode' and get to work on their new situation.

The last three phases of the Change Curve – experiment, decision, and integration – are much more rationally driven. People have essentially gotten over the emotional side of the change and their focus is on acting and moving forward. In managing through these phases, you will be able to focus more on tasks, scheduling, and deliverables. The integration is first successful when the productivity and engagement is higher than before the acquisition.

NOVO NORDISK PERSPECTIVE

Seen from the acquiring side, in particular the Data Science organisation at Novo Nordisk, Dicerna was fast in accepting the new premise of being part of a much bigger company. However, from the Novo Nordisk side there was not complete clarity on the acquisition integration in operational manners.

We have found that a stronger plan, and communication hereof, could have made the integration more straight forward. Seen from outside it might have been smaller items, but the accumulations of them resulted in some vagueness in the initial phase of the acquisition on both sites.

Once the aims and goals became clear and were communicated from the acquiring side the integration took speed. There were a lot of optimism and people started experimenting on both sides – somehow the depression phase was ignored or at least not observant. There were for instance established a "buddy go-to" system for each Dicerna employee with a corresponding person from Novo Nordisk, tightening the collaboration closely together and merging ways-of-working across the Atlantic. Also, more frequent business travel came in place (the Covid restrictions also limited that in the beginning), and people experimented at all levels.

Over time it became obvious that even though the denial phase for Dicerna Data Science colleagues were not outspooking, other parts in both Dicerna and Novo Nordisk organisation were in a different phase in the Kübler-Ross Change curve. That gave different challenges while experimenting, since leaving the old Dicerna process, procedures, and system behind and embracing the Novo Nordisk ways going forward are inter-dependent of each other. Thus, a lot of effort needed to be made to align people across both organisations, to work towards the same common aim, goals and point of integration.

Summarizing our learnings and recommendation: as an acquiring company there should be a clear communication and a high-level transition plan for the acquired company and its employee. This should be in place already at the time of acquisition, or very shortly after. In the example of Dicerna, this could have been that Dicerna should have continued their "business-as-usual" work with the aim of ensuring timely submission of the already advanced new drug application (NDA) to FDA, using their existing process and system. At the same time the Novo Nordisk organisation should in *parallel*, work towards the full integration within Novo Nordisk process and systems for future projects starting up. Worries and anxiety could have been avoided with a clear plan for integration with a clear communication.

DICERNA PERSPECTIVE

Regarding the initial stage in the Kübler-Ross Change Model, from our experience at Dicerna, we had not felt shocked and in denial when we first heard the acquisition news. Because the M&A is not rare in the Boston area, our feelings might be better described as uncertainty, suspicion, and listlessness during those times. There was a jump to excitement/experimentation when we met with leaders from Novo Nordisk and heard about projects and initiatives the company is working on. People begin to accept what is happening and are more hopeful and willing to try it in the acquisition procedure. They become more proactive and start seeking out information on the potential positive benefits of change. Our location on the change curve has moved in a back-and-forth pattern, though the midpoint has steadily climbed. A back followed this to uncertainty/listlessness, a feeling that we did not know how to move forward as integration activities in other areas progressed. The model, while helpful, should not be relied on as the sole predictor of individual reaction.

From the Dicerna side, we summarize the following points that might help both sides to face another possible acquisition in the career path

- Build a short-term goal and long-term goals regarding different functions and projects
- Hold the positive attitude to the integration stages and be patient with the progress or decision
- Be patient with management hesitation and uncertainty
- Find the effective communication channel
- Use the integration procedure as an opportunity for growth

OVERALL CONCLUSION

Big pharmaceutical companies are acquiring smaller pharmaceutical companies for multiple reasons, either to create new promising development programmes from the asset or gaining fast access to new products already developed by the smaller companies. For a data scientist this presents new opportunities and challenges. When receiving new data packages from the acquired companies it is important to have a strategy and methodology for evaluating the data received. Equally important is ensuring that the data package received from the acquired company is comprehensive, containing all needed deliverables and reflecting the results correctly. The data packages must be evaluated towards a submission ready deliverable across authority requirements.

An acquisition can have different causes of action, taking over only the products and the related data or integrating the acquired company fully into the acquiring company. The M&A of Dicerna belongs to the latter. From the acquired company's perspective, it's important to work towards a cultural understanding and be open-minded towards working differences in standards, procedures, and systems. From the acquiring perspective, being open, fair, and honest is the best way to communication with and retain the acquired employee if keeping the acquired company employee is one of goals of the acquisition. Meanwhile, it is beneficial that the acquiring company have a strategic plan to handle human resource loss during the procession.

Every organization going through the M&A process must have a clear communication and integration program to ensure the smooth flow of knowledge and information during the entire process. Novo Nordisk has established elaborate communication paths among employees and management, bridging the gap between new employees and bringing them into the new work environment. When the organization encourages the employees, puts in measures to break walls, pays attention to the human capital perspective, and keeps perceived organization support at optimal levels. Therefore, the employees are expected to reciprocate by working harder, being more productive, providing feedback, and engaging in other activities that fast-track the achievement of organizational goals and objectives.

In a future where M&A most likely will become more frequent, the role of the data scientists both in the acquired and the acquiring companies will be of great business critical importance. The data scientist's ability to bridging the scientific data package evaluations and the change management perspectives in M&A situation, with the aim of a submission of a new product will be essential.

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APPENDIX

Below are listed recommended high-level items that should be consider while evaluating insourced study data, including two easy to print check of table for documents and data related deliverable to expect from the acquired company or CRO.

SDTM AND ADAM

1. Evaluate if the specifications are adequate, reasonable and if the code creating the ADAM programs follows the specifications.
2. Evaluating the actual implementation of code and programming style and accessing the submission readiness of the programs, while keeping in mind that these programs are not to be 100% sponsor compliant.
3. A suggested first focus could be on the variables which are derived making sure that business rules are correct and implemented in accordance with the protocol and statistical analysis plan (SAP).
4. Ensuring traceability from specification, documentation, and actual code in the ADaM programs and macros used is key.
5. Consider running each ADaM program to ensure they can run and compare the final dataset with the delivered ADaM datasets, thus preparing for Q&A (Questions & Answers) and other situations where future use of the ADaM data will be needed. This also ensures that all relevant macros are available.

TABLES, LISTINGS, FIGURES (TLF)

1. Check if all TLF output and programs are available in the data package and if a TLF specification file is available, that this matched the TLF output and programs provided and matched the specification in the SAP and protocol.
2. Starting with the primary analyses and major endpoints TLF output and programs, these should also be available in the define file section of analysis result metadata if analysis results metadata (ARM) is available and continuing to a selected number of TLF output and programs across the clinical study appendix sections.
3. The selected TLF programs should be checked for correct use of ADaM datasets and variables, including the correct use of flagging and arm variables which must match the TLF titles.
4. The implementation of computation of descriptive statistics should be evaluated for code robustness and correctness towards the ADaM model used.
5. Check derivations in TLF programs and evaluate if these are according to the specification. There could be hardcoding in the TLF programs, these should be identified and evaluated against documentation in database lock (DBL) minutes or ADaM specification.
6. As for the ADaM, selected TLF programs should be run to ensure they can run produce the output matching the TLF output.

MACROS

Macros are equally important to evaluate both for ADaM programs and TLF programs. The macros should be part of the data package and described in the analysis data reviewers guide (ADRG). The same requirements as for ADaM and TLF evaluation applies, and submission readiness is equally important as some or all macros may be submitted.

REVIEWER'S GUIDES

1. The data reviewer's guides for both SDTM (cSDRG) and ADaM (ADRG) should be based on the PHUSE templates, having the mandatory sections filled out. The evaluation should assess whether there is sufficient purposefully duplicate limited information found in other submission documents, thus providing a single point of orientation to the SDTM and ADaM datasets and ADaM programs. Furthermore, the ADRG should provide a context for analysis datasets and terminology supported by the define file. Soundness of explanations for any unusual data points or unique circumstances i.e., hardcoding or data handling should be evaluated.
2. The SDTM and ADaM conformance findings from pinnacle 21 checks should be provided in a summary and explained in a degree which is acceptable by sponsor requirements for submission. If several trials are part of the evaluation, the same check should have a similar explanation and if not, reason for not having the same explanation, should be apparent.
3. In addition, the ADRG should include a description of the data reproducing the primary analyses, datasets, and major endpoints (as supplement to the analysis results metadata, ARM).

DEFINE FILES

The define files for SDTM and ADaM describing the metadata is an especially important part of the dataset submission. The define files should be evaluated to have sufficiently documented data definitions and derivations including the ARM specification in the ADaM define.

It is important to ensure that links to other documents, such as aCRF, SAP, ARM tables and outputs, protocol, and data reviewers guides (cSDRG and ADRG) are working.

Table 1. Documents to request from the acquired company or CRO.

Documentation to request	Available	Comments and Status
Document with specifications of deliverables	☐	
Protocol	☐	
Synopsis	☐	
Statistical Analysis Plan (SAP)	☐	
Clinical study report	☐	
Result meeting slides	☐	
Randomization scheme or code	☐	
Programming specification for ADaM and TLF programs (ensure eTMF documentation for review of programs)	☐	
Study Data Standardization Plan	☐	
DBL minutes	☐	
Study Data Standardization Plan (SDSP) document or the Clinical Data Interchange Standards Consortium (CDISC) exchange standards and terminology standards information needed for the SDSP	☐	
BIMO (Bioresearch Monitoring Program Information) components	☐	
BIMO package	☐	
Financial information	☐	
Investigator information	☐	
Protocol Deviations (PD) data	☐	
Regulatory meeting minutes (stat and programming related decision)	☐	
Pre BLA/NDA meeting	☐	
End of phase x meeting	☐	
CRO collaboration	☐	
Contracts	☐	
Specifications	☐	
Deliverables	☐	

Table 2. Data related deliverable to expect from the acquired company or CRO.

Deliverables to expect	Available	Comments and Status
Are the data deliverables in CDISC or Legacy data (complete the legacy check list)	☐	
SDTM (Study Data Tabulation Model)		
SDTM specification	☐	
Metadata-level	☐	
Data (sas7bdat, xpt)	☐	
aCRF	☐	
Define.xml	☐	
cSDRG both as word and pdf	☐	
SDTM Pinnacle 21 conformance checks	☐	

ADAM (Analysis Data Model)		
ADaM specification	☐	
ADaM datasets (sas7bdat, xpt)	☐	
ADaM metadata	☐	
Define.xml (ARM)	☐	
ADRG both as word and pdf	☐	
ADaM Pinnacle 21 conformance checks	☐	
ADaM programs (sas)	☐	
Macros used in ADaM programs (sas)	☐	
external data used (excel etc.)	☐	
TLF	☐	
TLF specification	☐	
TLF programs (sas)	☐	
TLF outputs (txt, rtl)	☐	
TLF appendixes, complied TLF (doc, pdf)	☐	
Macros used in TLF programs (sas)	☐	
External data used (excel etc.)	☐	
ClinicalTrials.gov	☐	
Specification	☐	
Output files (xml, txt)	☐	
SAS programs	☐	
Investigator's Brochure (IB)	☐	
Specification	☐	
SAS programs	☐	
Output	☐	
Development Safety Update Report (DSUR) or Periodic Safety Update Reports (PSUR)	☐	
Specification	☐	
SAS programs	☐	
Output	☐	
Pooled datasets across trials for Integrated Summary of Effectiveness (ISE) and Integrated Summary of Safety (ISS)	☐	
Specification	☐	
Datasets	☐	
SAS programs	☐	
Output	☐	
Bioresearch Monitoring Operations (BIMO)	☐	
Specification	☐	
Clinsite dataset	☐	
Define.xml	☐	
BIMO Data Reviewers Guide (BDRG) both as word and pdf	☐	
SAS programs	☐	
Output	☐	