

Big Pharma acquires Biotech

– perceptions from the
clinical data scientists'
point of view

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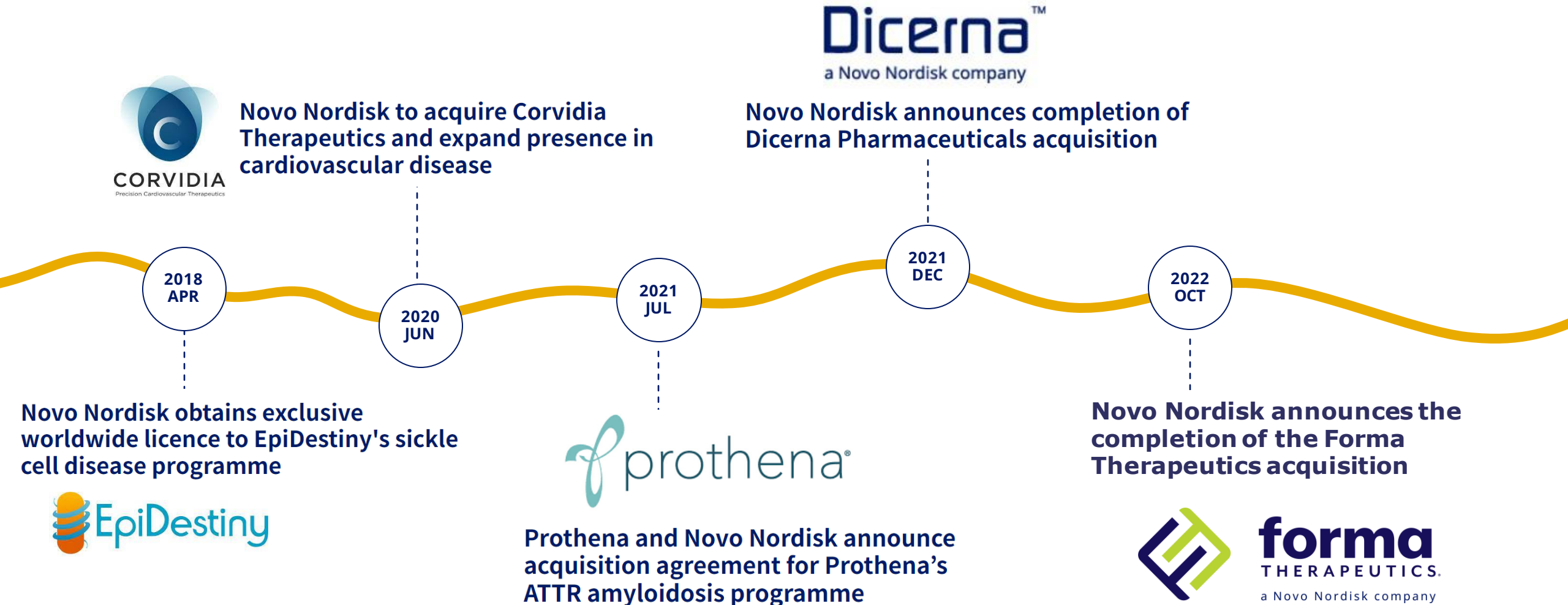
Disclaimer

“Views and opinions expressed are those of the speakers and not necessarily Novo Nordisk.”

Agenda

1. The evaluation process and its aspects
2. Acquired company: thoughts and reflections
3. Joint view and perspective of integration

History of Novo Nordisk acquisitions



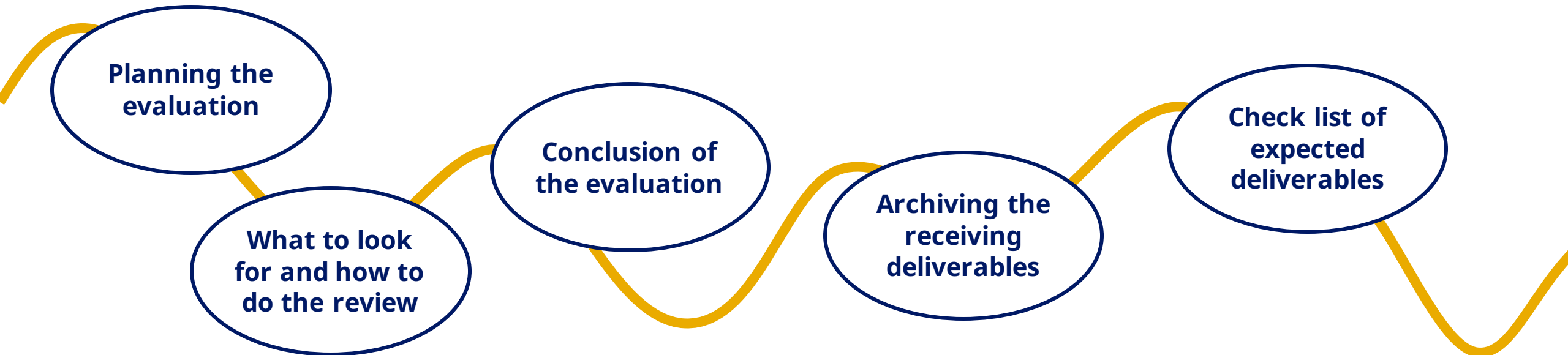
The evaluation process and its aspects



Main points of the evaluation

1 **Review and evaluation of the acquired biostatistical deliverables**
Programs, datasets and other documentation (ADRG, define, protocol, SAP etc.)

2 **Give guidance on collaboration and expected deliverables**



Getting started on the right foot

Planning the evaluation

1

Risk profile

Start creating a risk profile, what is your risk tolerance, number of players

2

Issue tracker

Overview and tracking of issue found and resolved

3

Timelines for planned deliverables

It can be a race to the finish line

Risk appetite
(RANGES FROM 0-110 km/h):
the amount of risk you are willing to accept to achieve a submission ready package



Risk tolerance
(RANGES FROM 110-120 km/h):
the acceptable deviation from your risk appetite.

Unacceptable risk
(120 km/h and above)

Issue No.	Source	Review initials	Type	Sub-type	Action	Issue text
Example	Output	Novo Nordisk	Tabels	tae.sas	Query	Please include footnote xxx in table 8.2.11

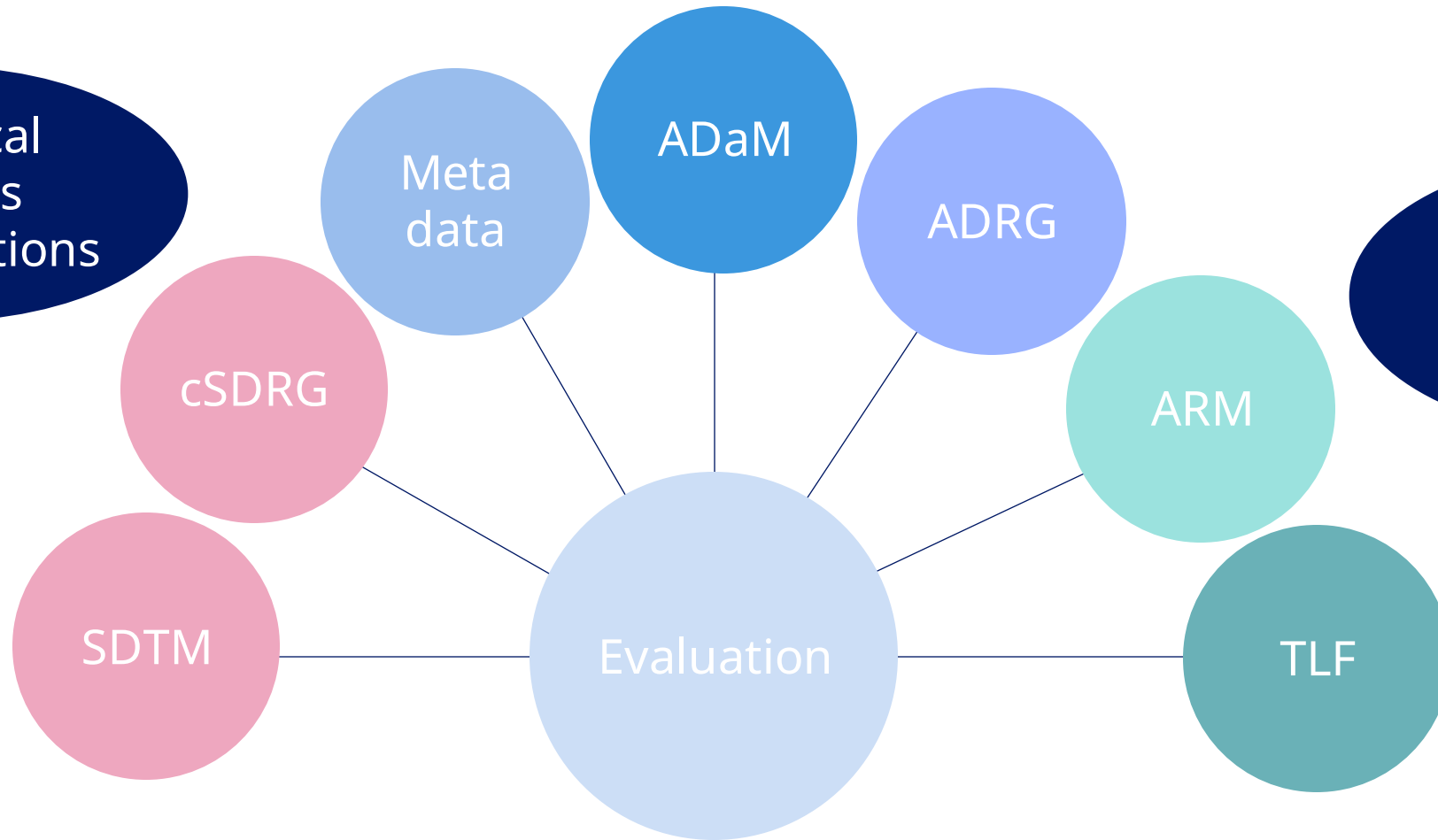
Illustration of risk tolerance in a practical setting

Ensuring that the acquired company or CRO closes issues found

The evaluation package

What to look for and how to do the review

Statistical analysis considerations



Programming specification

Slow



Fast to market

Let management know what you think

Conclusion of the evaluation

Conclusion



1

The overall conclusion of the evaluation should be presented to management.

Issue tracker



2

Stakeholder alignment with ex. RA, TM and DM
Use the issue tracker actively for decisions taken

What's the cost



3

Decide on how and when to resolve issues as a cost will be add to you or the CRO
Present the cost

Take a risk



4

Take a risk and wait to time of submission, which trials be submitted

Archive it You won't remember in 5 years time

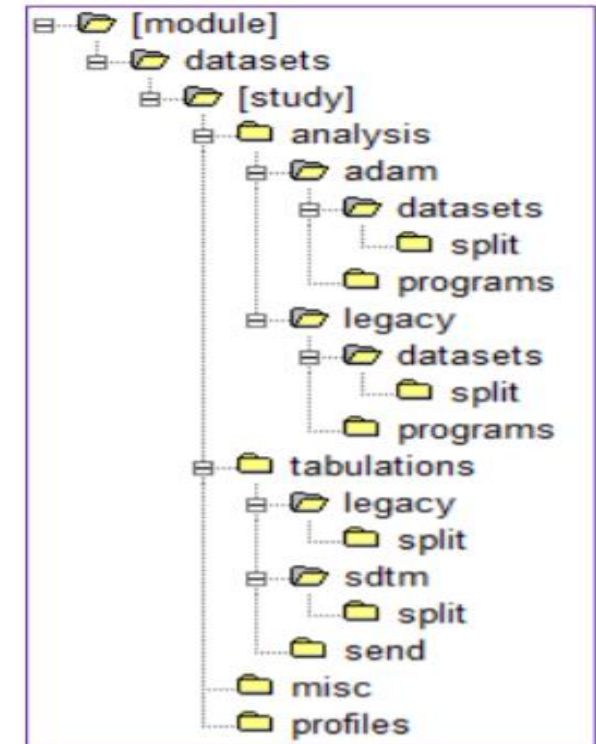
1 Track the deliveries from the company or CRO

2 Put the submission deliverables into a M5 folder structure

3 Trial management will handle the TMF deliverables , review the archived data science deliverables

4 Ensure input from trial programmer and trial statistician

Archiving the
receiving
deliverables



Get the complete data package

Check list of
expected
deliverables

Documents to request from the company or CRO

1

Documentation	Available
Document with specifications of deliverables	☐
Protocol	☐
Synopsis	☐
SAP (statistical analysis plan)	☐
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 CDISC exchange standards and terminology standards information needed for the SDSP	☐
BIMO (Bioresearch Monitoring Program Information) components	☐
BIMO package	☐

Data package related deliverable to expect

2

Deliverables	Available
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*	
ADaM specification	☐
ADaM datasets (sas7bdat, xpt)	☐
ADaM metadata	☐
Define.xml (ARM)	☐
ADRG both as word and pdf	☐
ADaM Pinnacle 21 conformance checks	☐

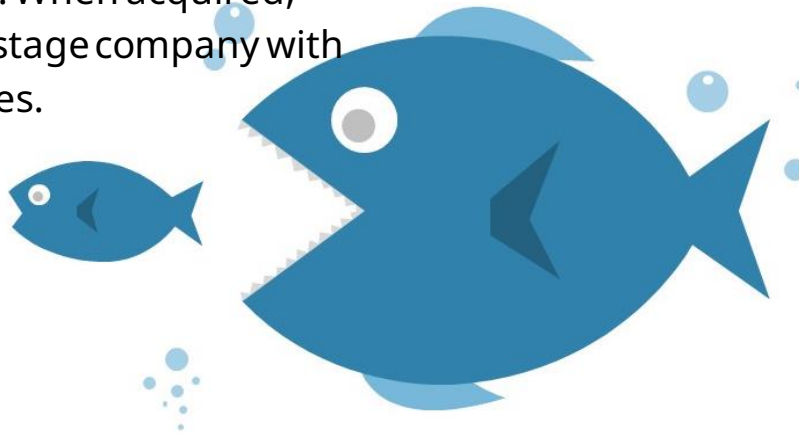


Acquired company Thoughts and reflections

The Dicerna perspective on the acquisition

Dicerna

Dicerna is a biopharma company that uses GalXC™ and GalXC-Plus™ technologies to create targeted RNAi therapies for both rare and common diseases. When acquired, Dicerna was a clinical-stage company with just over 300 employees.



Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. It has more than 55,000 people in 80 offices around the world, and market products in 170 countries. The main research areas are diabetes and other serious chronic diseases such as obesity, and rare blood and rare endocrine diseases.

The assets of acquiring Dicerna



The geographies to expand

The Boston/Cambridge area is hot biotech innovation hub in the world



The new technology to bring in

Dicerna GalXC™ and GalXC-Plus™ RNAi drug discovery platform



The talent to retain

Dicerna employee



The products to add

The acquisition eliminates the milestones and royalties it would need to pay Dicerna for partnered candidates, also acquire other Dicerna pipelines

Dicerna employee reactions to acquisition

"The Only Constant in Life Is Change."- Heraclitus

- Afraid for Job security

Change is a constant in business, but that doesn't make it any easier to deal with. Acquisition impact the employees or the workers the most. It is a well-known fact that there are bound to be layoffs whenever there is a merger or acquisition.

- Resisting the oncoming change
- Polish the resume
- Stressed and upset about the inconvenience
- Excited about the challenge
- Ready to make adjustments

The challenges to Dicerna employee

Compliance & regulations

Compliance issues are likely to occur as the two business units have different levels of compliance. Policies, regulations, and guidelines are required to implement to ensure organizations to run smoothly

Role and responsibilities

Novo Nordisk has a more delicate role division, acquired employee must be stated or even trained about their roles & responsibilities in the new working place.

Career development

The Intergrated new employee also hope to grow in the new working environment. how much career opportunity ahead?

Culture integration

Novo Nordisk and Dicerna share multiple core values : open and honest, ambitious, accountable, and treating everyone with respect. But they have divergent understanding to the acquisition

Increasing visibility

Geographic location and different world time zone cause the acquired part hard to attend the department All-hand conference

Processing standards & procedure

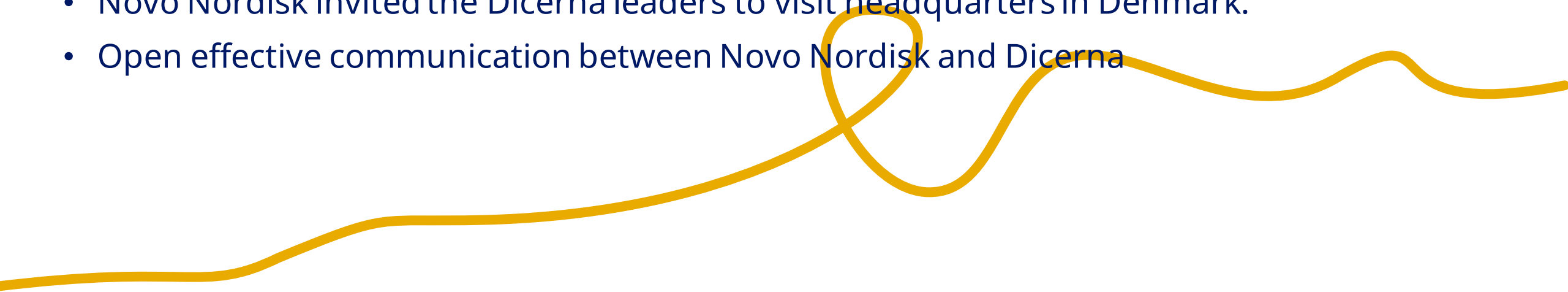
Novo Nordisk has a multi-level decision-making framework, meticulous procedure for clinical data handling and reporting.

IT integration

A lack of synchronization throughout the IT infrastructure can cause difficulties with everyday business processes, producing complications and slowing down overall operation



Novo Nordisk's efforts after the acquisition

- Upper management visited the Boston site as early as possible after the acquisition news was released. They reassure job security and help Dicerna employees focus on the business's success.
 - Invest resources to form an integration group to lead integrating activity cross functions.
 - Retained the core Dicerna employees
 - Assign Novo Nordisk's buddy to each of Dicerna employee
 - Novo Nordisk invited the Dicerna leaders to visit headquarters in Denmark.
 - Open effective communication between Novo Nordisk and Dicerna
- 

Lessons learned from the acquisition and integration – from Dicerna perspective

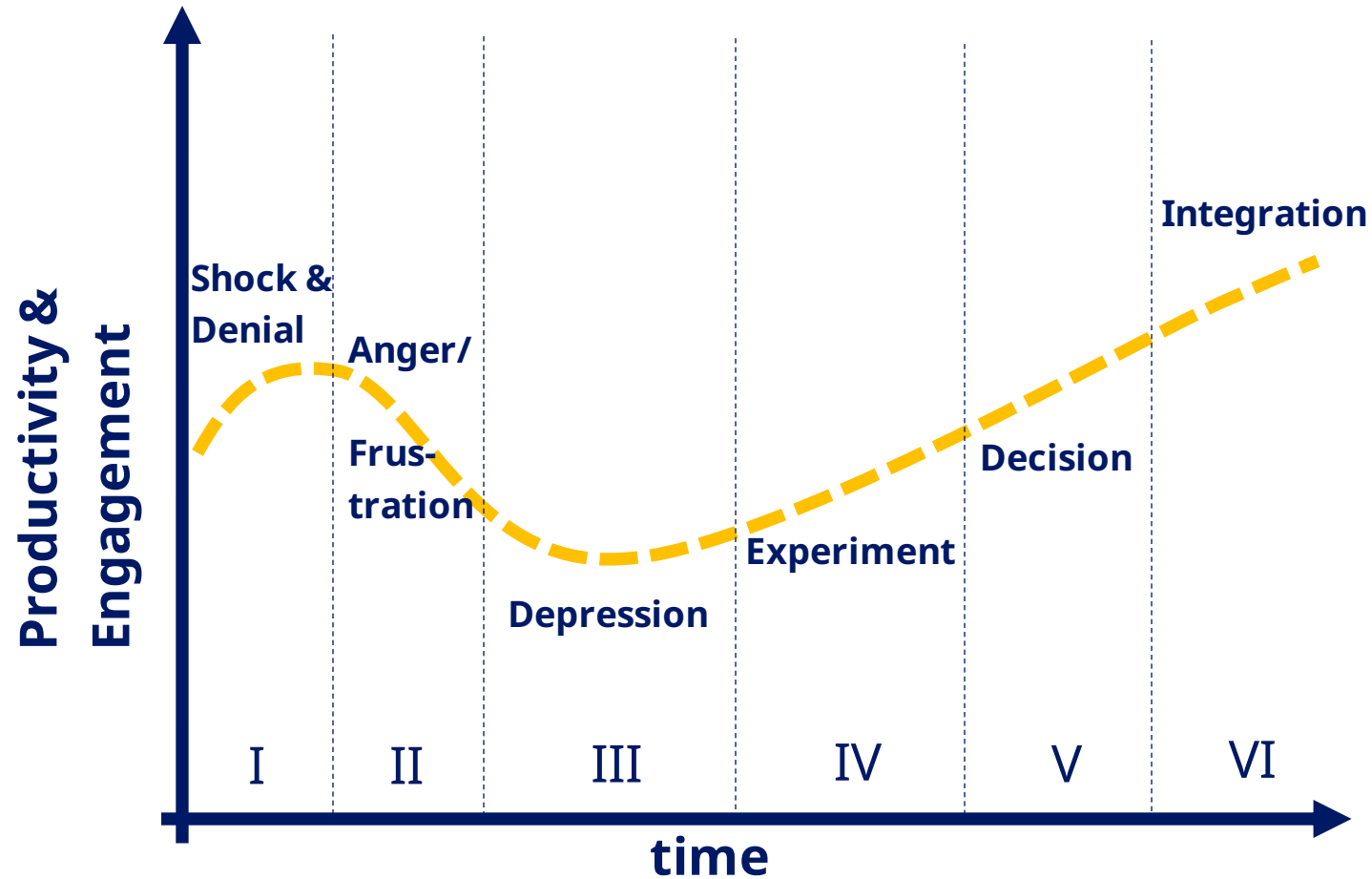
- Change is usually inevitable, so we need to figure out where we stand and embrace challenges and changes.
- Build a short-term goal and long-term goals regarding different functions and projects
- Hold the positive attitude to the integration stages and be patient with the progress or decision
- Be patient with management hesitation and uncertainty
- Find the effective communication channel
- Use the integration procedure as an opportunity for growth



**Joint view and perspective of
integration**

Integration of Biotech and large Pharma

Trying to understand the change it brings: Kübler-Ross model



Ambition of fully integration

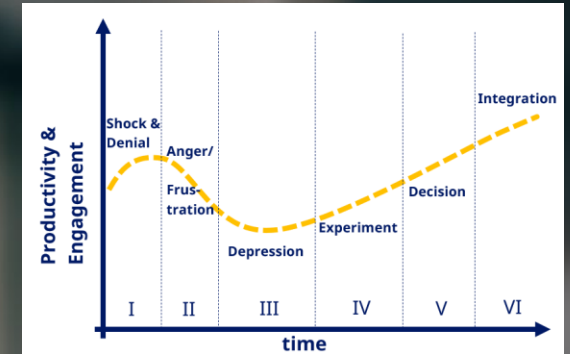
The two perspectives:

7. A year later: Are the two companies fully integrated now? Are all dots connected?

2. How was the acquisition received in Novo?
4. How did you try to avoid the depression?
6. Was the entire Data Science organisation at the same place in the change curve?



1. How was the news about the acquisition perceived amongst your colleagues?
3. What frustrations did you encounter during the integration?
5. Where would you see Dicerna being currently in the change-curve?



Our take away messages

What have we learned and how do we see our future?



M&A the “new black”

- Merger & acquisition within pharma is “**daily life**”
→ Part of Novo Nordisk **strategy**
- For data scientist M&A also comes with a lot of **new opportunities**
- Face the **positive site** of it



Obtaining quality

- The acquired data packages needs to be evaluated with the **focus of submission** hereof
- Be **open** and **transparent** of
 - decisions
 - issues
 - riskwithin project organization



Integration

- Have a **clear strategy** for integration in place as closed to when the M&A happens
- Clear and **strong communication** is key
- Have a **focus on the people** – let them find a new equilibrium
- Have a **short term** aim with little change and a **long term** aim where change can be assessed

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Thank you for your attention!

Any question....?

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