GDPR IN CLINICAL TRIALS & NON-INTERVENTIONAL STUDIES

From a Sponsor's Perspective

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Novo Nordisk at a glance

Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care.

This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic diseases: haemophilia, growth disorders and obesity.

PRODUCTS MARKETED IN
170 COUNTRIES

AFFILIATES IN COUNTRIES 80

R&D CENTRES
IN CHINA, DENMARK, INDIA, UK AND US

EMPLOYS APPROXIMATELY
43,200 PEOPLE

DKK 112 BILLION
IN TOTAL REVENUE

STRATEGIC PRODUCTION SITES
IN BRAZIL, CHINA, DENMARK, FRANCE AND US

APPROXIMATELY
207,000
SHAREHOLDERS

SUPPLIER OF NEARLY
HALF OF THE WORLD'S INSULIN

29,200,000
PEOPLE USE OUR DIABETES CARE PRODUCTS

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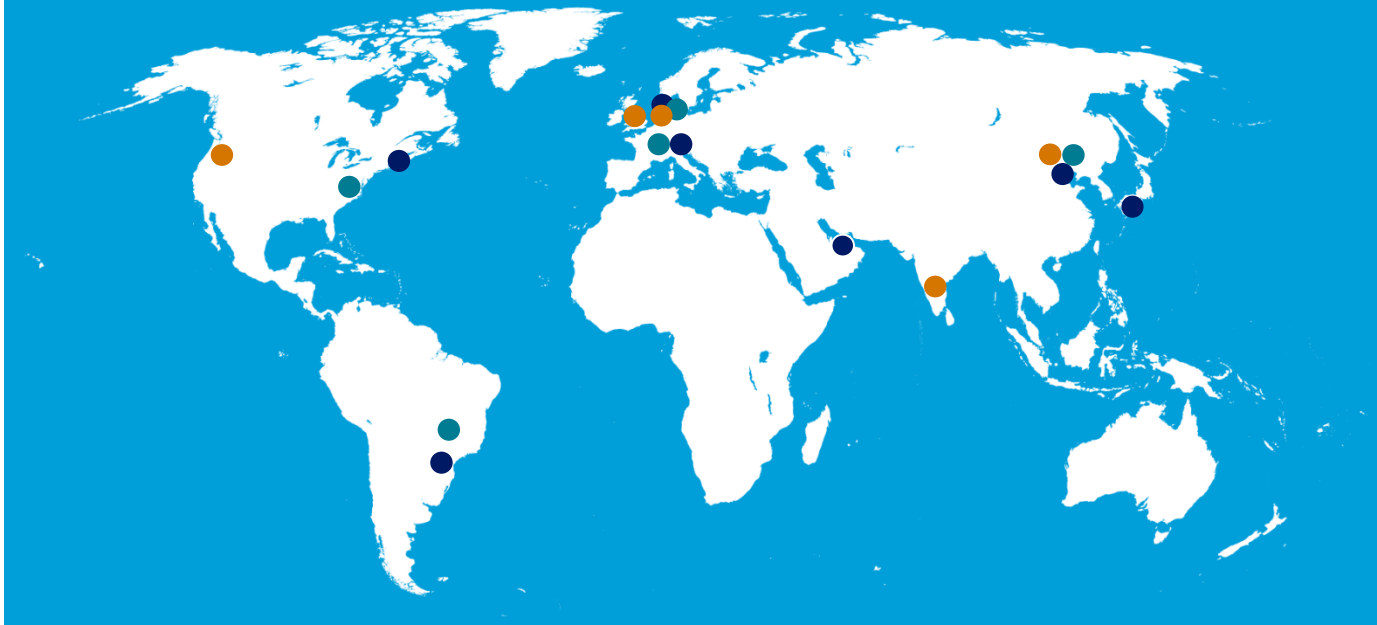
Our global presence

NOVO NORDISK AFFILIATES IN

80 COUNTRIES

NOVO NORDISK MARKETS ITS PRODUCTS IN

170 COUNTRIES WORLDWIDE



CORPORATE HEAD QUARTER
BAGSVÆRD, DENMARK

NORTH AMERICA OPERATIONS HQ
PLAINSBORO, NJ, US

INTERNATIONAL OPERATIONS HQ
ZÜRICH, SWITZERLAND

REGIONAL OFFICES

- BEIJING (CHINA)
- SAO PAOLO (LATIN AMERICA)
- TOKYO (JAPAN & KOREA)
- COPENHAGEN (EUROPE)
- DUBAI (AFRICA, ASIA, MIDDLE EAST & OCEANIA)

STRATEGIC PRODUCTION SITES
BRAZIL, CHINA, DENMARK, FRANCE, AND THE US

R&D CENTRES
CHINA, DENMARK, INDIA, UK, AND THE US

Agenda

1. What is it all about?
2. GDPR in Novo Nordisk
3. GDPR in the context of trial conduct
4. Laying the foundation for your data processing
5. Collecting personal data
6. Wrapping up & future use of data
7. Learnings from living with GDPR

What is it all about?

Setting the stage

The aim of a Clinical Trial or Non-Interventional Study

1. Prove the benefits outweigh the risks
2. Demonstrate the efficacy of the drug
3. Produce high-quality data for making informed decisions in healthcare
4. Show superiority to other current treatments

The aim of the General Data Protection Regulation:

1. To reinforce data protection rights of the individual
2. Reduce administrative burden by aligning across EU
3. Ensure transparent processing of data

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GDPR in Novo Nordisk

Personal data protection is about respect

More than 25,000 people participate in a Novo Nordisk clinical trial each year.

Novo Nordisk clinical trials are conducted at more than 5,000 trial sites.

There are more than 50 countries around the world that host Novo Nordisk clinical trials.

At any given time, there may be more than 100 active Novo Nordisk clinical trials.

Essential 6

We treat everyone with respect

We respect the trust given to us by **patients**, **HCPs** and **employees**, as such we promote

Respectful use of personal data

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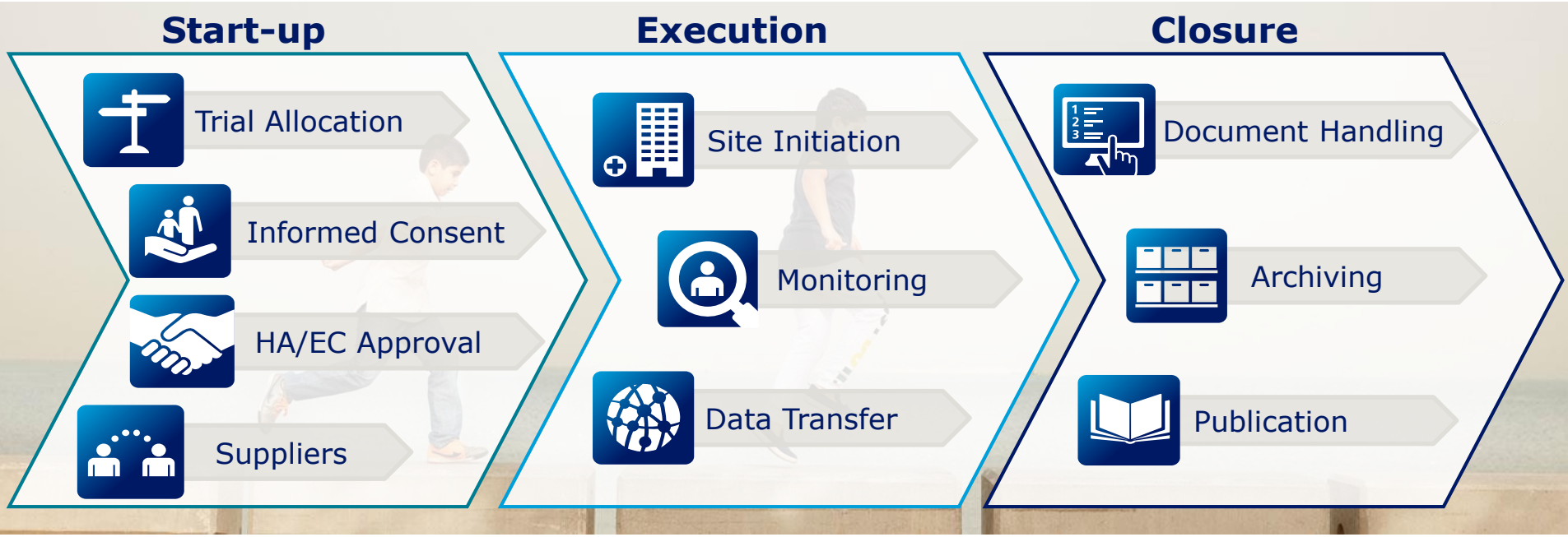
GDPR in the Context of Trial Conduct

Where is the main impact?



HA: Health Authorities
EC: Ethics Committee

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Laying the Foundation for your Data Processing

Trial start-up

Trial Allocation
Where will the trial be conducted and what data do you need to collect?

Informed Consent
What is the legal basis for collecting patient data and how can you use that data?

HA/EC Approval
What are the rights of the data subject and what can be considered scientific research?

Suppliers
Who is the data controller vs. data processor and how do you define the responsibility split?

HA: Health Authorities
EC: Ethics Committee

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Collecting Personal Data

Trial execution

Site Initiation
What is the relationship and responsibility of sponsor and site?

Monitoring
How do you communicate and follow-up with individual sites?

Data Transfer
How, where and to whom do you share data?

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Wrapping up & Future use of Data

Trial closure

Document Handling
How many copies and versions of the same data do you actually need?

Archiving
When can data be considered archived?

How long do you store your data?

Publication
How do you ensure transparency while maintaining data privacy?

Can data be used for future scientific research?

Legal Affairs Denmark

Learnings from living with GDPR

Summary

What are the biggest challenges:

- Creating a privacy mindset
- Making GDPR practical
- Determining the risks
- Everyone is a GDPR expert
- Adequate IT systems and procedures
- Research collaboration
- Reuse of data

What we need to move forward:

- Unilateral definition of legal basis for personal data collection related to health research for Clinical Trials & NIS
- Consistency in GDPR interpretation and rights of the trial participants
- Technical solutions to allow for privacy by design/default
- Data sharing standards

VICTOR DA SILVA MELCUNAS
Brazil
Victor has severe haemophilia A

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NIS: Non-Interventional Study