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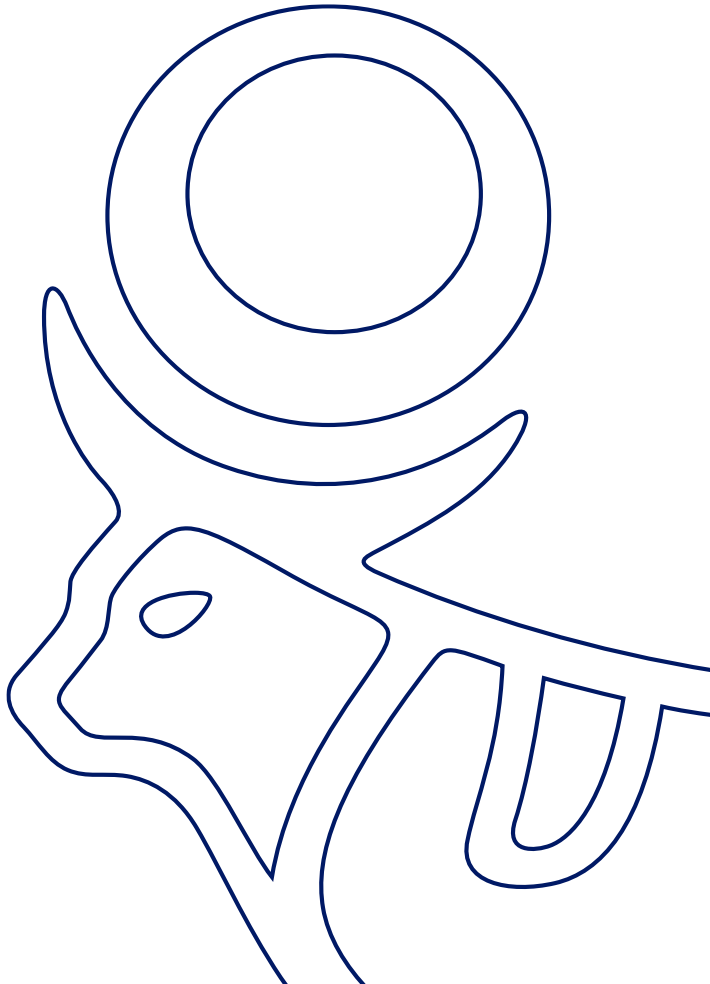
novo nordisk®

From manual expense to digital flow

DCC & DCR



Heidi Foldal

2025.10.08

Novo Nordisk at a **glance**

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark.

Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes.

We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease.

1. https://companiesmarketcap.com/pharmaceuticals/largest-pharmaceutical-companies-by-market-cap/ (As of 6 August 2025).

Supplier of nearly

50%

of the world's insulin

Net sales

290.4

billion DKK

Affiliates in

80

countries

More than

77,349

employees

Investing more than

52

billion DKK in R&D

R&D facilities in China, Denmark, UK, US and India

Strategic production sites in Belgium, Brazil, China, Denmark, France, Italy and US

Globally, serving more than

45.2

million people living with serious chronic diseases

A top ten

pharma company measured by market value[1]

Introduction

- Corporate metrology process:
- Purpose – to ensure reliable and traceable measurements for critical processes
- Strategic goals – to remove manual transfer of data and to have FAIR and relevant data available for decision-making
  - Running pilots for implementation of Digital Calibration Certificates (DCC) and Digital Calibration Request (DCR)

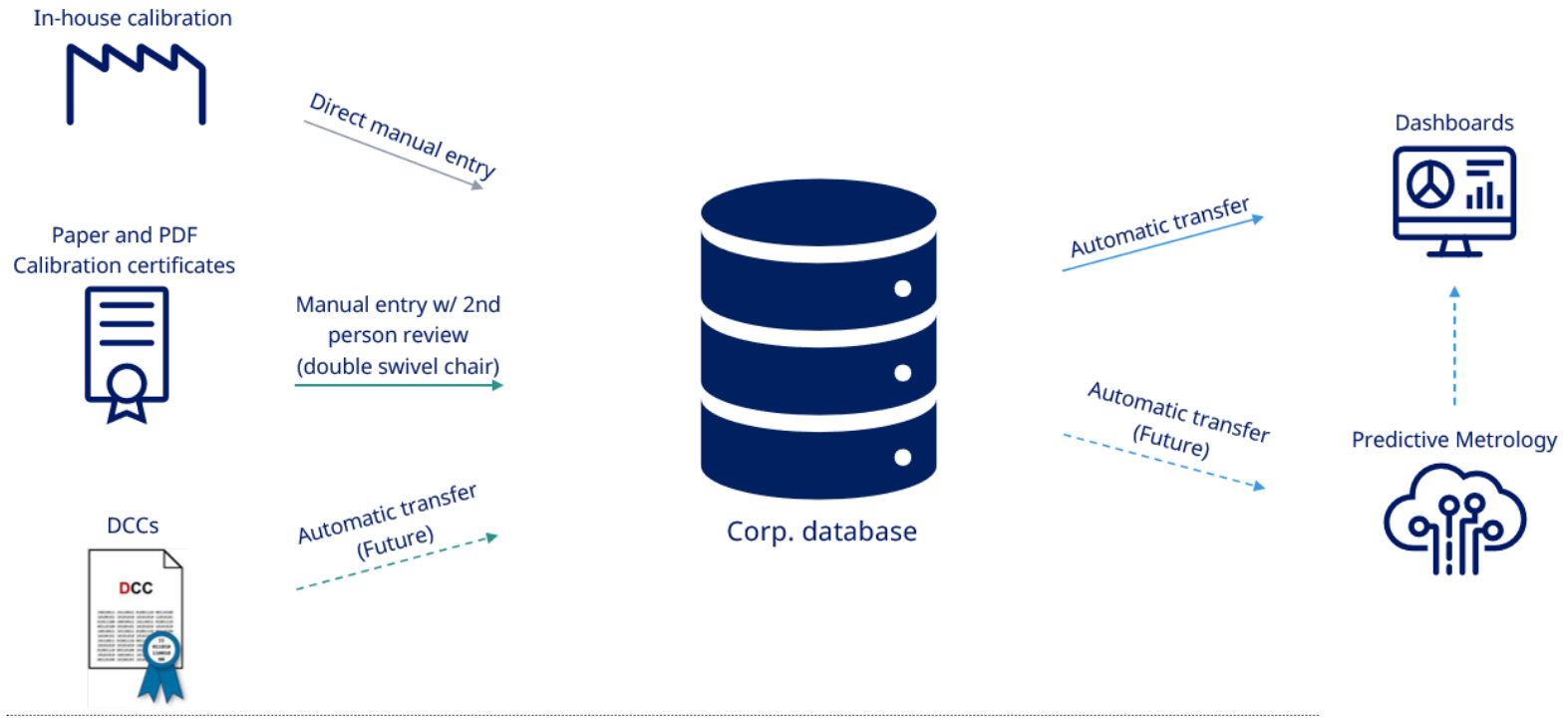
Novo Nordisk Calibration Programme

High level

- Define what to measure
- Identify the requirements for the measurand
- Calibration requirements for the measuring equipment is based on the requirements for the measurand
- Calibration intervals are specified based on a risk assessment assessing impact, probability and mitigation
- If measuring equipment does not comply with requirements – Deviations are created to evaluate the use in the entire period back to the last passed calibration
- Outsourcing:
  - Execution of calibration can be outsourced
  - Responsibility of result evaluation cannot be outsourced
  - Conformity statements in calibration certificates are not wanted
  - Calibration certificates must be delivered to Novo Nordisk

Calibration Data Flow

- Corporate IT system manages calibration program
- Centralized database records results from Novo Nordisk and suppliers
- Manual entry of calibration data into the system
- IT system evaluates if a calibration is pass or fail
- Performance monitored using dashboards



Future goals

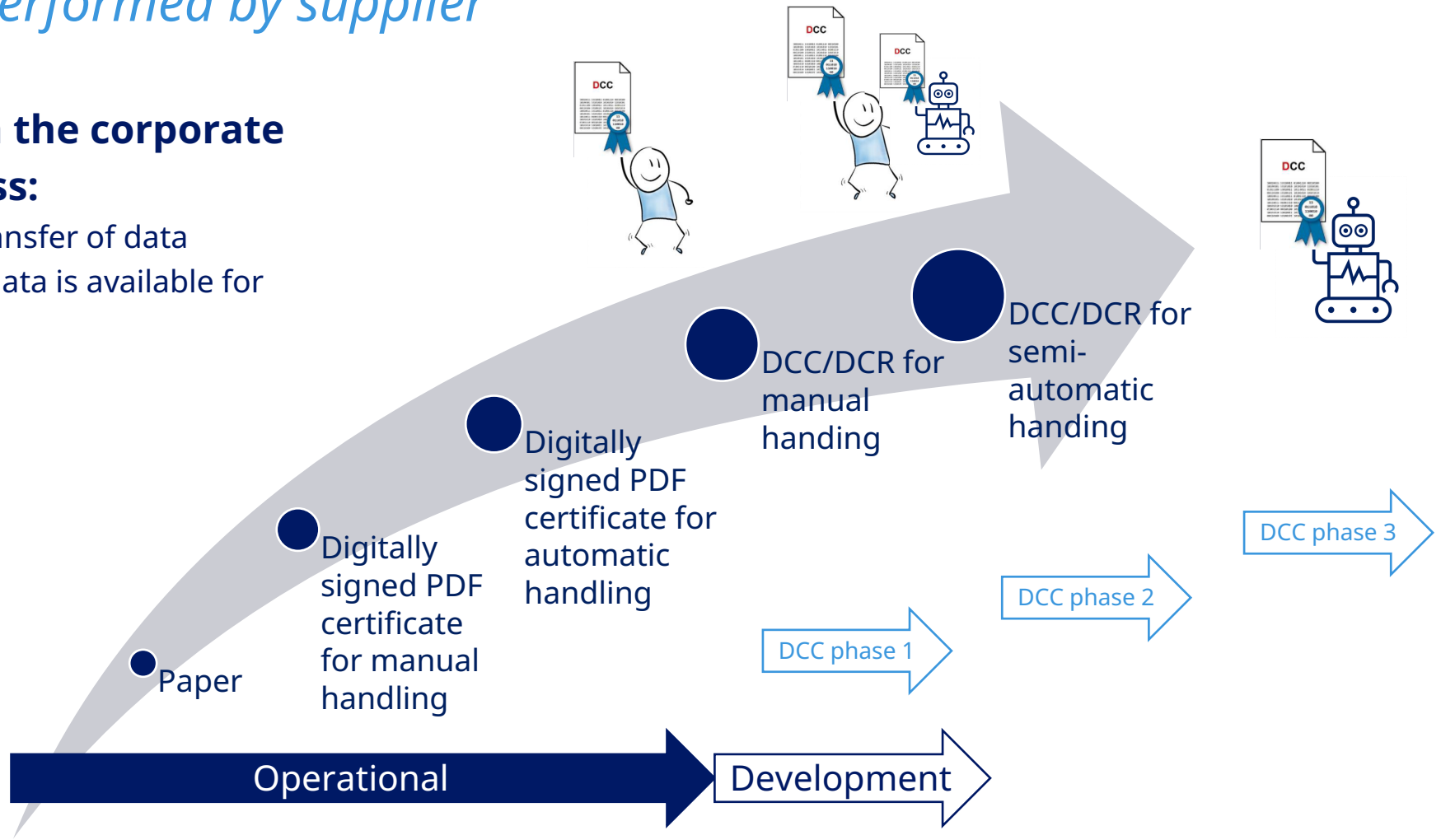
- Predict equipment failure
- Optimize calibration program for efficiency and avoid over-processing and under-processing

Digitalisation and Automation Journey

- Calibration performed by supplier

Strategic goals in the corporate metrology process:

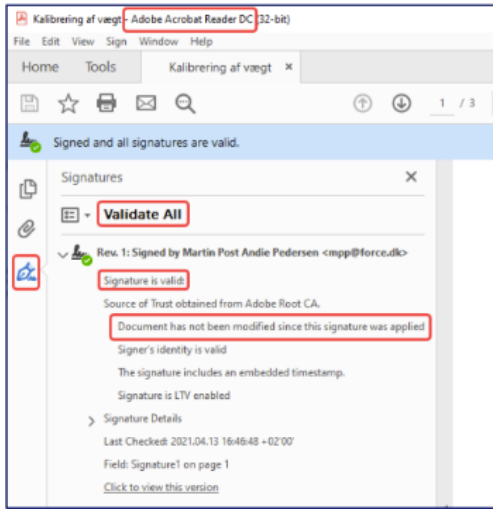
- Remove manual transfer of data
- FAIR and relevant data is available for making decisions



Digitalisation and Automation Journey

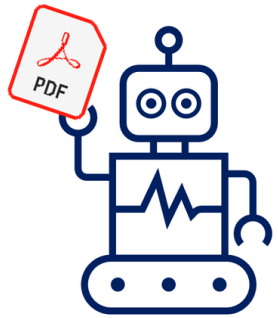
Operational – digitally signed PDF calibration certificates

- Guidance document established for receiving digitally signed PDF certificates
- Corporate requirements managed by record management process
- Contracts established with 10 Danish and 3 Chinese suppliers
- Signature(s) on PDF certificate verified against corresponding root certificate
- Use of Adobe AATL program for robust solution



Digitalisation and Automation Journey

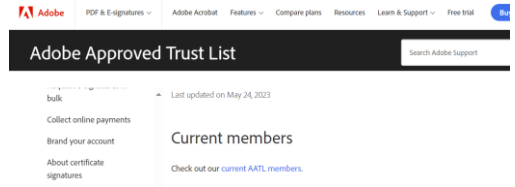
Operational – RPA solution for digitally signed PDF calibration certificates



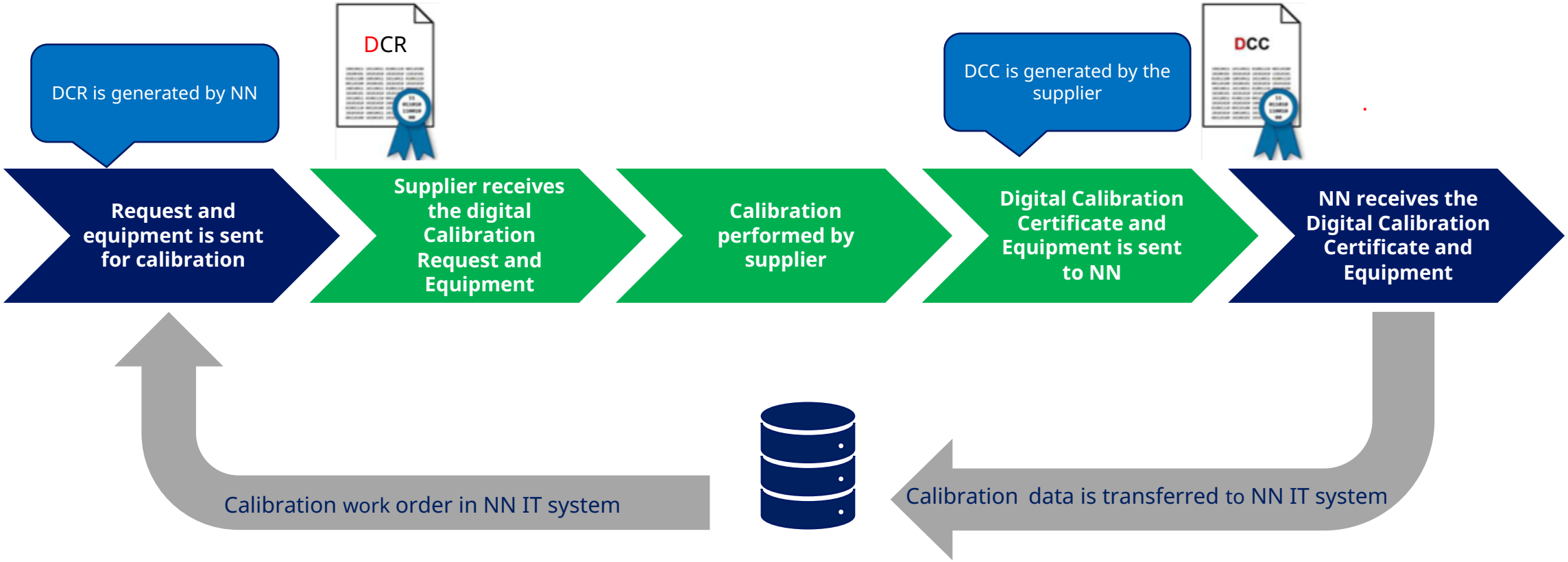
- Performing the data integrity verification is not a simple activity for all employees
- The corporate automation team has created an RPA solution to receive and archive digitally signed PDF certificates

Supplier performs the calibration → Supplier sends calibration certificate to BOT → BOT handles the certificate → BOT notifies the NN user

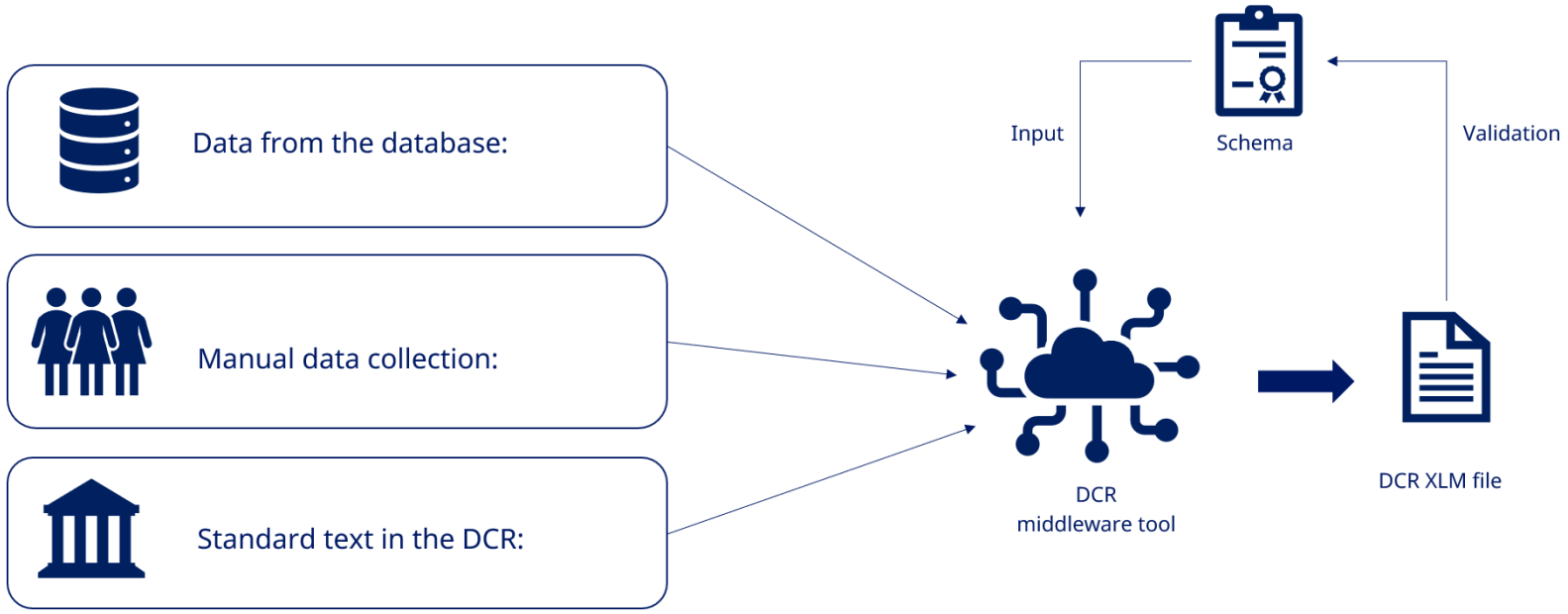
- Preconditions:
  - Agreement with supplier
  - Mail body requirements – the PDF certificate is not machine readable, but certificate metadata is needed for the archiving process
  - Signature root certificate is available in AATL (Adobe Approved Trust List)



DCR and DCC workflow



DCR pilot



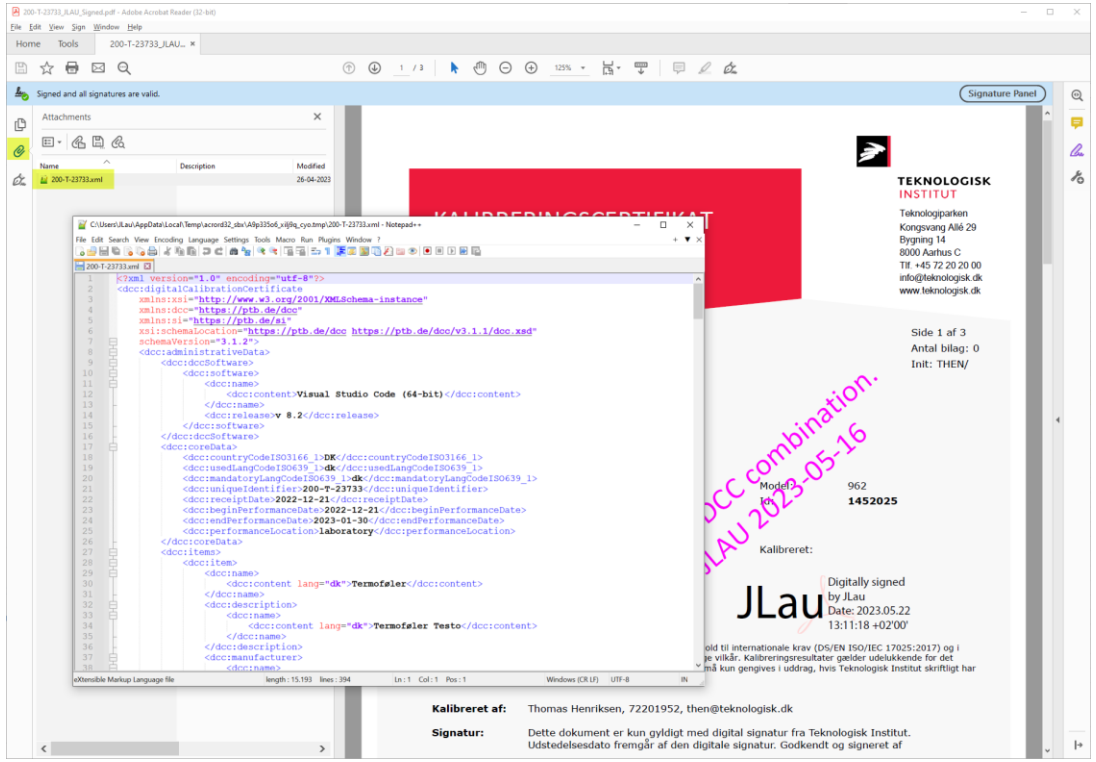
DCR Test Case

- The DFM NMI of Denmark developed the schema.
- Novo Nordisk produces a DCR using the DFM schema.
- The Danish Technological Institute is verifying whether they can process the DCR XML file.

GitHub - TC-IM-1448/DCC-Tables

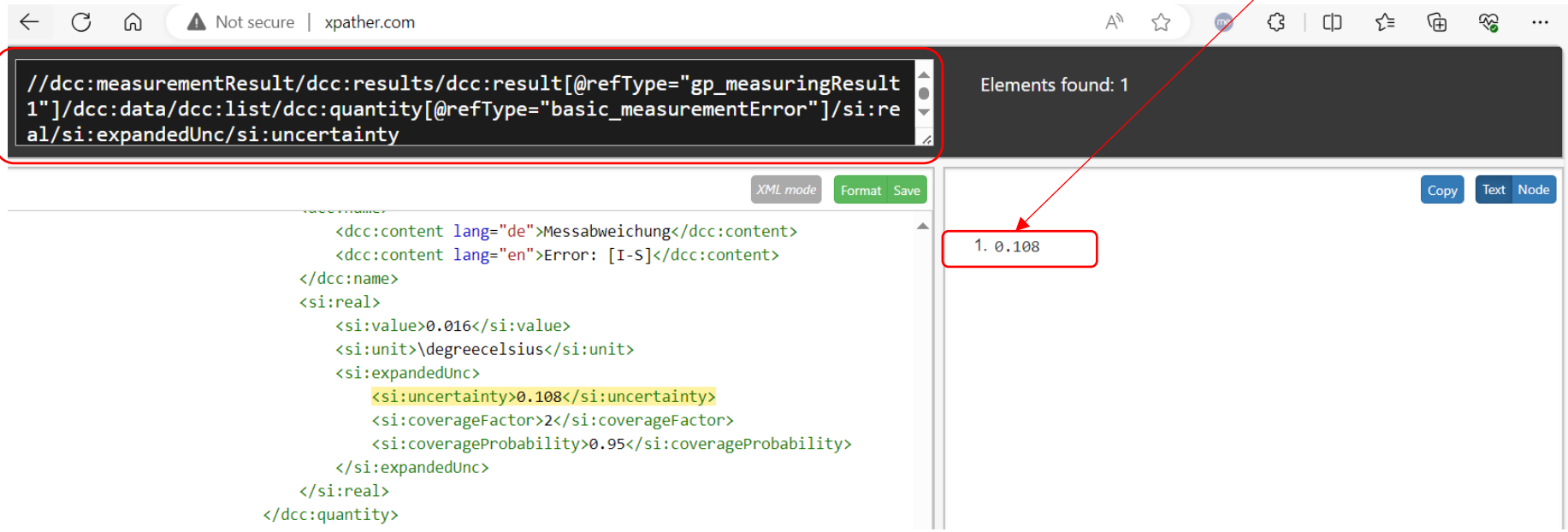
DCC – Phase 1

- Apply experience from work with digitally signed PDF calibration certificates
- Start by having suppliers embed XML files to the PDF as an attachment
- Retain the ability to present the PDF (human readable) during inspection and audit
- Running pilots with Danish suppliers for implementation of DCC and DCR



DCC Data Extraction Example

- Using xpather.com for Data Extraction to extract individual data from DCC XML file
  - The xpath sting below corresponds to the data search of:
    - The uncertainty value of the measurement error of the first calibration point



Mapping of Dataflow from DCC to NN IT System

Xpaths need to be consistent, well defined and objective

- If an XPath leads to multiple query results, the development of the middleware will become more complex, consequently increasing the risk of failure.
- More Xpaths for the calibration results:
  - //dcc:quantity[@refType="basic_referenceValue"]/si:hybrid/si:realListXMLList
  - //dcc:quantity[@refType="basic_referenceValue"]/si:hybrid/si:realListXMLList[2]

Complexity

```
<dcc:data>
    <dcc:list refType="gp_table1">
        <dcc:quantity refType="basic_referenceValue">
            <dcc:name>
                <dcc:content lang="de">Bezugswert</dcc:content>
                <dcc:content lang="en">Reference value</dcc:content>
            </dcc:name>
            <si:hybrid>
                <si:realListXMLList>
                    <si:valueXMLList>267.074 278.167 300.204</si:valueXMLList>
                    <si:unitXMLList>\kelvin</si:unitXMLList>
                </si:realListXMLList>
                <si:realListXMLList>
                    <si:valueXMLList>-6.076 5.017 27.054</si:valueXMLList>
                    <si:unitXMLList>\degreecelsius</si:unitXMLList>
                </si:realListXMLList>
            </si:hybrid>
            <dcc:measurementMetaData>
```

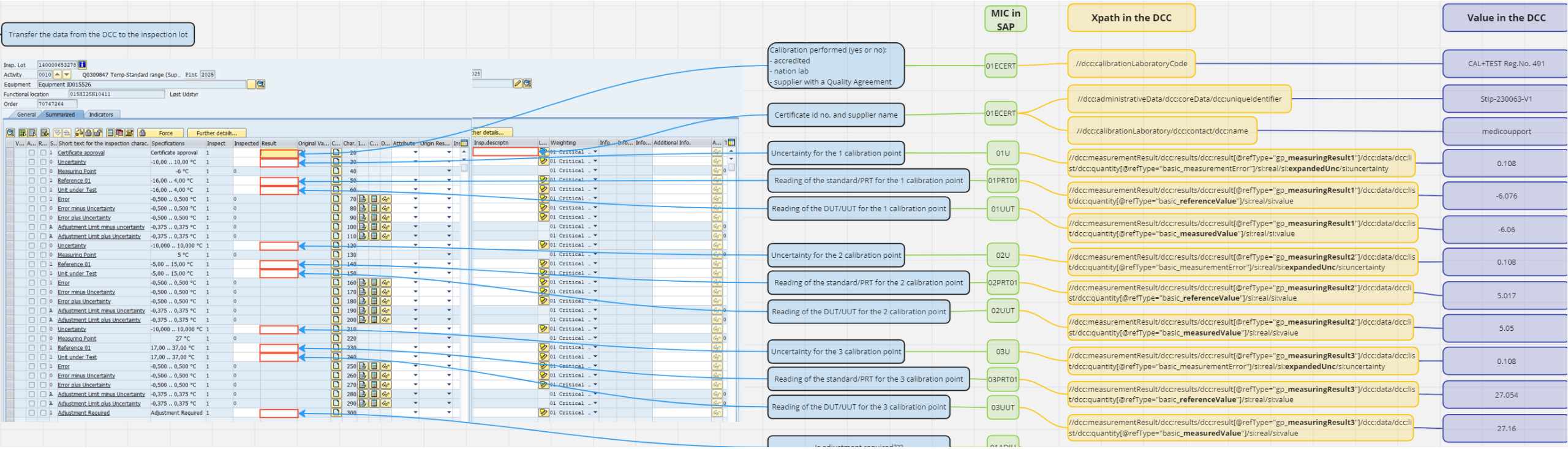
DCC Example

Calibration results **must** be uniquely identifiable

- Clear and unambiguous data path
  - Ample metadata to ensure correct data transfer
- Collaboration with PTB
  - Example: 3-point temperature calibration
  - Structure of DCC - *result element representation*

```
<dcc:result refType="gp_measuringResult1" id="r01">
    <dcc:name>
        <dcc:content lang="de">Messergebnisse</dcc:content>
        <dcc:content lang="en">Measuring results</dcc:content>
    </dcc:name>
    <dcc:data>
        <dcc:list>
            <dcc:quantity refType="basic_calibrationValue">
                <dcc:name>
                    <dcc:content lang="de">Kalibrierpunkt</dcc:content>
                    <dcc:content lang="en">Point</dcc:content>
                </dcc:name>
                <si:real>
                    <si:value>-6</si:value>
                    <si:unit>\degreecelsius</si:unit>
                </si:real>
            </dcc:quantity>
            <dcc:quantity refType="basic_referenceValue">
                <dcc:name>
                    <dcc:content lang="de">Bezugswert:</dcc:content>
                    <dcc:content lang="en">True Value: [S]</dcc:content>
                </dcc:name>
                <si:real>
                    <si:value>-6.076</si:value>
                    <si:unit>\degreecelsius</si:unit>
                </si:real>
            </dcc:quantity>
            <dcc:quantity refType="basic_measuredValue">
                <dcc:name>
                    <dcc:content lang="de">Angezeigter Messwert Kalibriergegenstand</dcc:content>
                    <dcc:content lang="en">Indicated: [I]</dcc:content>
                </dcc:name>
                <si:real>
                    <si:value>-6.06</si:value>
                    <si:unit>\degreecelsius</si:unit>
                </si:real>
            </dcc:quantity>
            <dcc:quantity refType="basic_measurementError">
                <dcc:name>
                    <dcc:content lang="de">Messabweichung</dcc:content>
                    <dcc:content lang="en">Error: [I-S]</dcc:content>
                </dcc:name>
                <si:real>
                    <si:value>0.016</si:value>
                    <si:unit>\degreecelsius</si:unit>
                    <si:expandedUnc>
                        <si:uncertainty>0.108</si:uncertainty>
                        <si:coverageFactor>2</si:coverageFactor>
                        <si:coverageProbability>0.95</si:coverageProbability>
                    </si:expandedUnc>
                </si:real>
            </dcc:quantity>
            <!-- generate from previous quantity Error + Uncertainty -->
            <dcc:quantity>
                <dcc:name>
                    <dcc:content lang="de">Messabweichung</dcc:content>
                    <dcc:content lang="en">Error + Uncertainty:</dcc:content>
                </dcc:name>
                <si:real>
                    <si:value>0.124</si:value>
                    <si:unit>\degreecelsius</si:unit>
                </si:real>
```

Mapping of Dataflow from DCC to NN IT System



Data Management

- Novo Nordisk needs to comply with the ALCOA++ PRINCIPLES
  - Secretariat of the Pharmaceutical Inspection Convention, PIC/S GOOD PRACTICES FOR DATA MANAGEMENT AND INTEGRITY IN REGULATED GMP/GDP ENVIRONMENTS (PI 041-1), 2021, Geneva, Switzerland
  - http://www.picscheme.org

PI 041-1 –Section 5.5.3 Risk (Good Guidance)

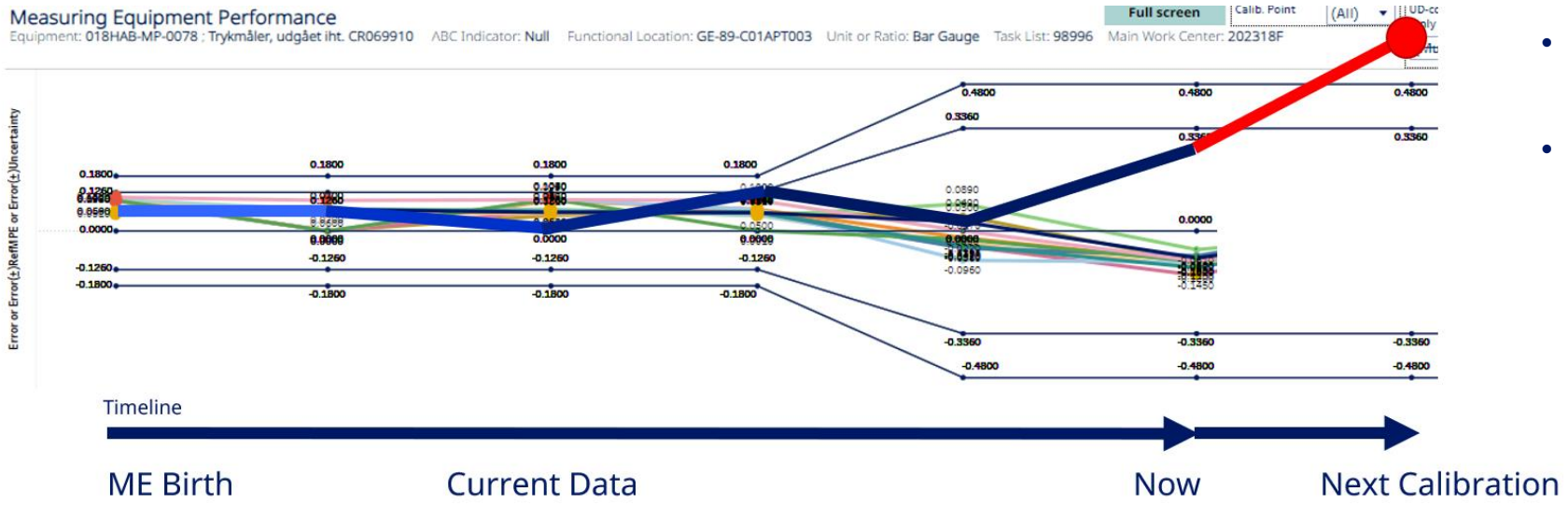
5.5.3 Examples of factors which can increase risk of data failure include processes that are complex, or inconsistent, with open ended and subjective outcomes. Simple processes with tasks which are consistent, well defined and objective lead to reduced risk.

At Novo Nordisk we prefer simplicity

WHY

- 20.000 supplier calibrations a year

- In average it takes **20 minutes** to transfer data from the calibration certificate to the IT system including second person review
- In average it takes **25 minutes** to transfer data from IT system to a letter to the supplier
  - 5% of all revised calibration certificates are revised due to errors in NN calibration request
- Trending on calibration data



- Transparent data insight via the dashboard
- Machine Learning under development to trend on data including metadata, and classify between equipment exhibiting systematic drift or not

Summary

Ensuring the successful global implementation of Digital Calibration Certificates (DCC) and Digital Calibration Requests (DCR) involves several critical factors:

- Establishing an **international standard** for DCC and DCR to maintain a unified framework and ensure data integrity.
- Adopting a **phased implementation** approach to manage changes effectively, allowing for thorough planning, monitoring, and adjustment.
- **Partnering** with collaborators who share the vision and can provide the necessary expertise and support.

These strategies are essential for promoting smooth operations, reducing errors, and achieving a seamless transition.

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