OncoDNA®
THE CANCER THERANOSTIC COMPANY

## International User Group Meeting

22nd and 23rd of April 2026

# One Panel, One Pipeline: Implementing OncoDEEP® for streamlined routine diagnostics


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Deputy Head of Molecular Pathology

# Sonic Healthcare Germany

## Federation Model



Each subsidiary remains medically leading while also being part of a larger network - with benchmarking and continuous quality assurance.

# Sonic Healthcare Germany

## MVZ Trier

A nationally recognized diagnostic institution for decades

Became part of Sonic Healthcare Germany in 2018

Certified by DIN EN ISO 9001; accredited by DIN EN ISO 17020

Disciplines: histology, cytology, molecular pathology

> 170 employees

> 300.000 patient/case numbers in FY25 (~ 1.200/day)

# MVZ Trier

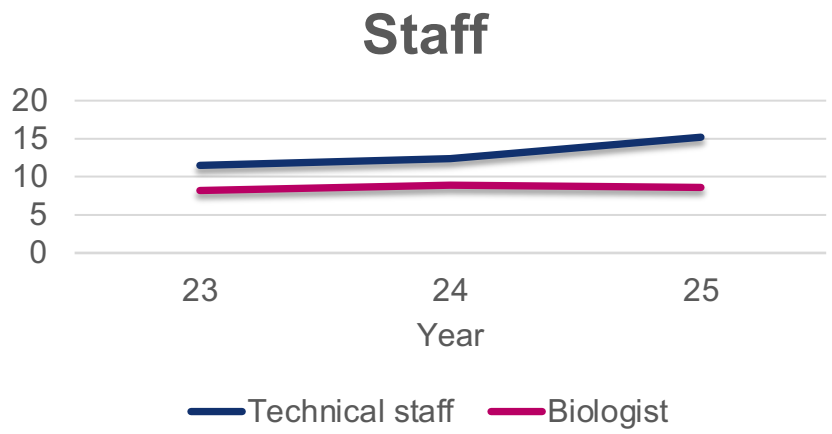
## Molecular Pathology

**Only** Molecular Pathology of Sonic Healthcare Germany

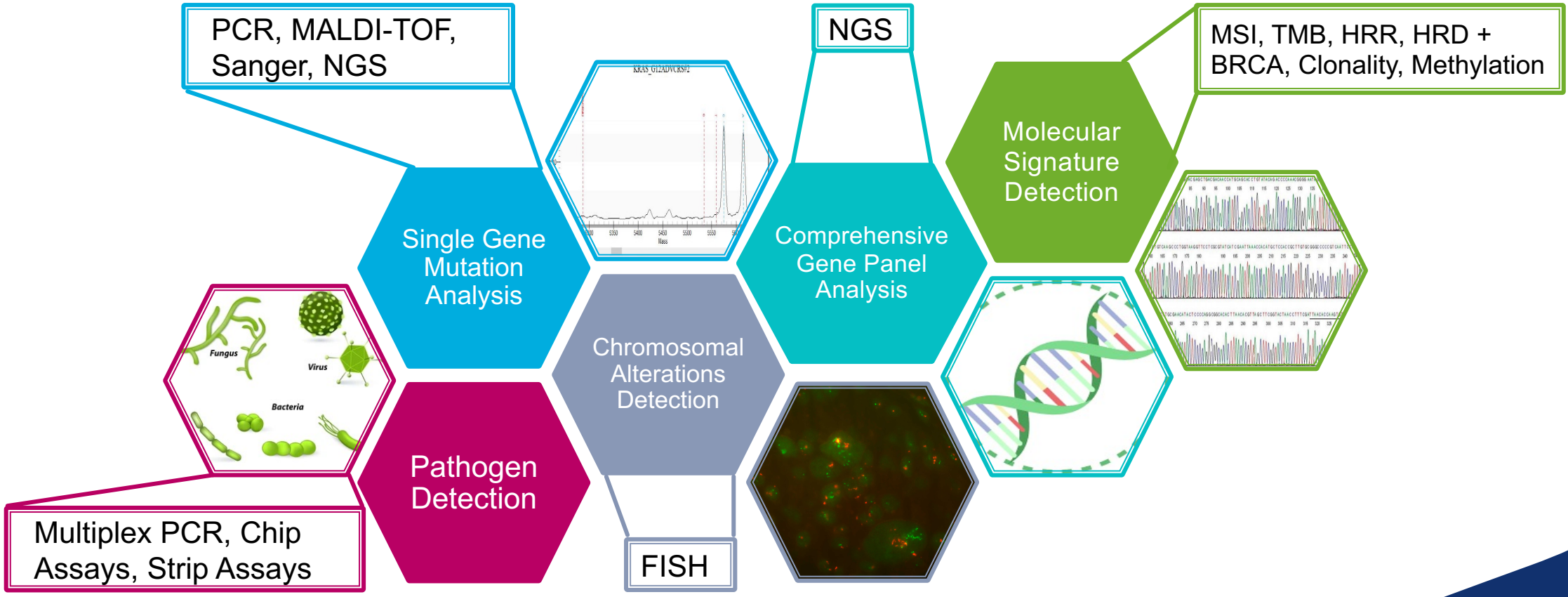
Founded in **2008**

Team:

- 9 biologists
- 15 technical staff



# Molecular Diagnostics – Our portfolio

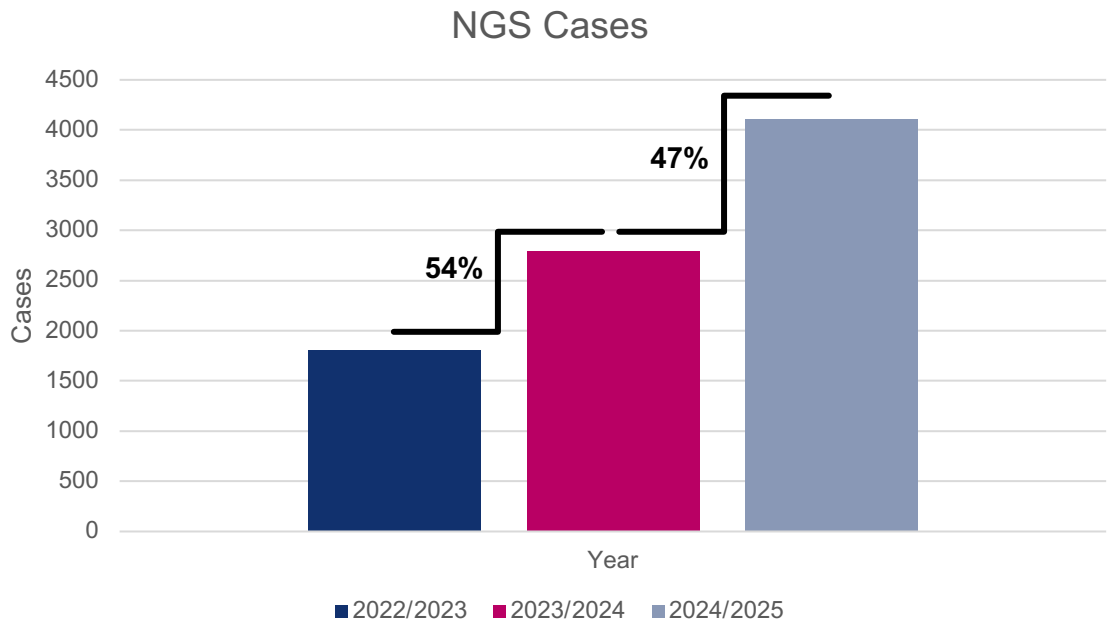


# Next Generation Sequencing

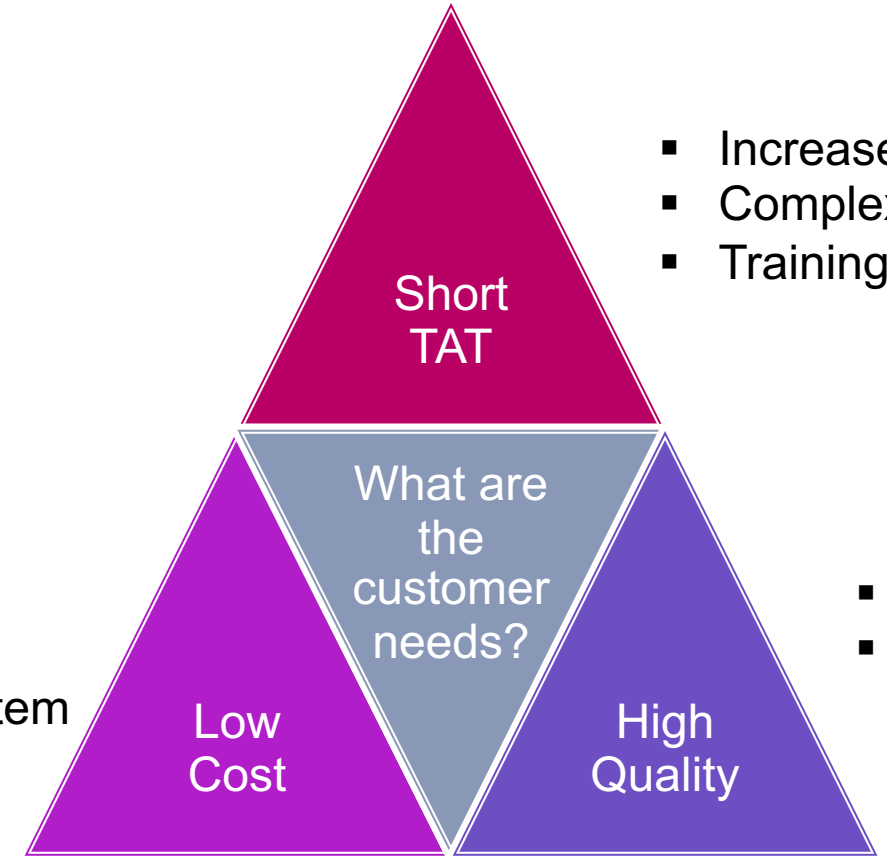
Molpath ~12.500 samples 2025

NGS  ~4.200 samples 2025

~ 32,8% of all samples are NGS
→ increasing



# Customer Expectations are our challenges




- Increased sample number
- Complex requests
- Training of technical staff

- Price Performance
- Automatization
- German healthcare system

- Poor quality of FFPE material
- Panels stringent quality requirement

→ Mission: Continuous improving



TAT= Turnaroundtime

# Implementing a new NGS-Pipeline

What was our baseline?

What are our needs?

What was our timeline?

What are the risks?

# What is our baseline – Start off 2025

Multiple NGS Panels
→ Thermo Fisher (FOCUS, BRCA and OCA)
→ AmoyDX (Classic, HRD and HRR)
→ Illumina (TSO500)

Multiple NGS Technologies
→ Amplicon based
→ Hybrid capture

Multiple Sequencing Platforms and bioinformatics pipelines
→ S5 (Ion Reporter and Torrent Suite)
→ NextSeq 550Dx and NextSeq2000 (ANDAS-Software, Basespace, ICA and ICI)

**Preferably an all-in-one solution.**

Poor quality of FFPE material
→ Panels with stringent quality requirement
→ It is not possible to follow a simple, structured procedure in the laboratory

Not all panels can be automated

Rising costumers' expectation

Analysis pipeline

Cost effective

IVDR compliance

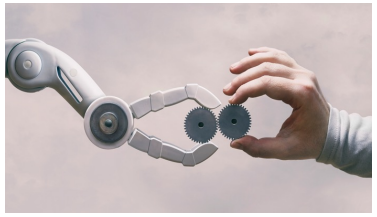
# What are our needs?

## Important

Increased performance
→ Samples with poor quality

Meet customers' rising expectations

Increased efficiency
→ **All-in-one solution**
→ Easier workflow
→ Automatization



Analysis pipeline

## Moreover

Increased report quality

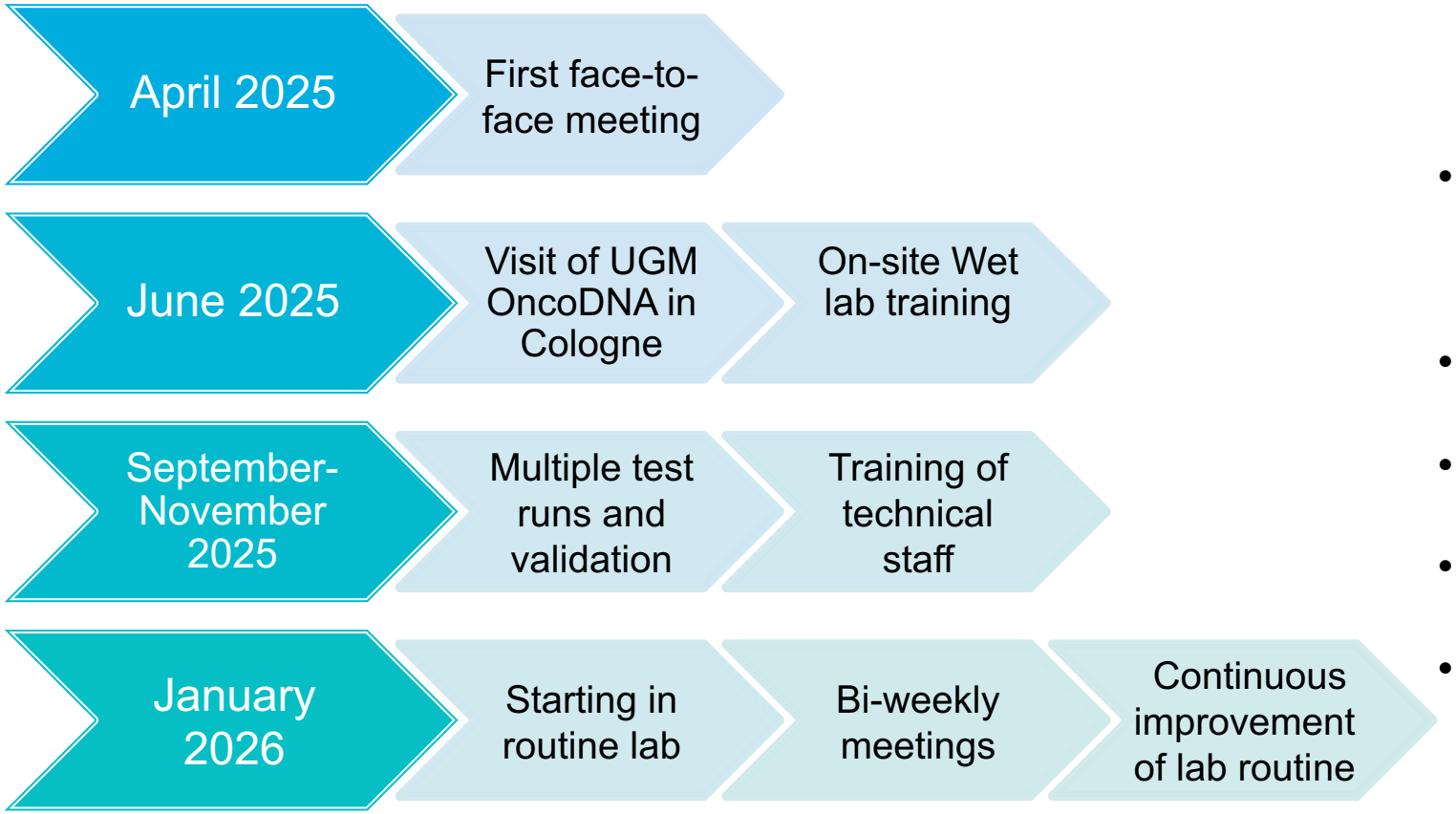
Cost effective

IVDR compliance

# Timeline

| | | | |
|---|---|---|---|
| April 2025 | First face-to-face meeting | | |
| June 2025 | Visit of UGM OncoDNA in Cologne | On-site Wet lab training | |
| September-November 2025 | Multiple test runs and validation | Training of technical staff | |
| January 2026 | Starting in routine lab | Bi-weekly meetings | Continuous improvement of lab routine |

# Timeline and Risks




- Functional, technical and operational requirements are not fully covered
- Unstable pipeline (from wet lab to final reporting)
- Key-person dependency
- Scalability and reliability
- Increased TAT
- Lack of automatization

# Implementing a new NGS-Pipeline

What was our baseline?

What are our needs?

What was our timeline?

What are the risks?

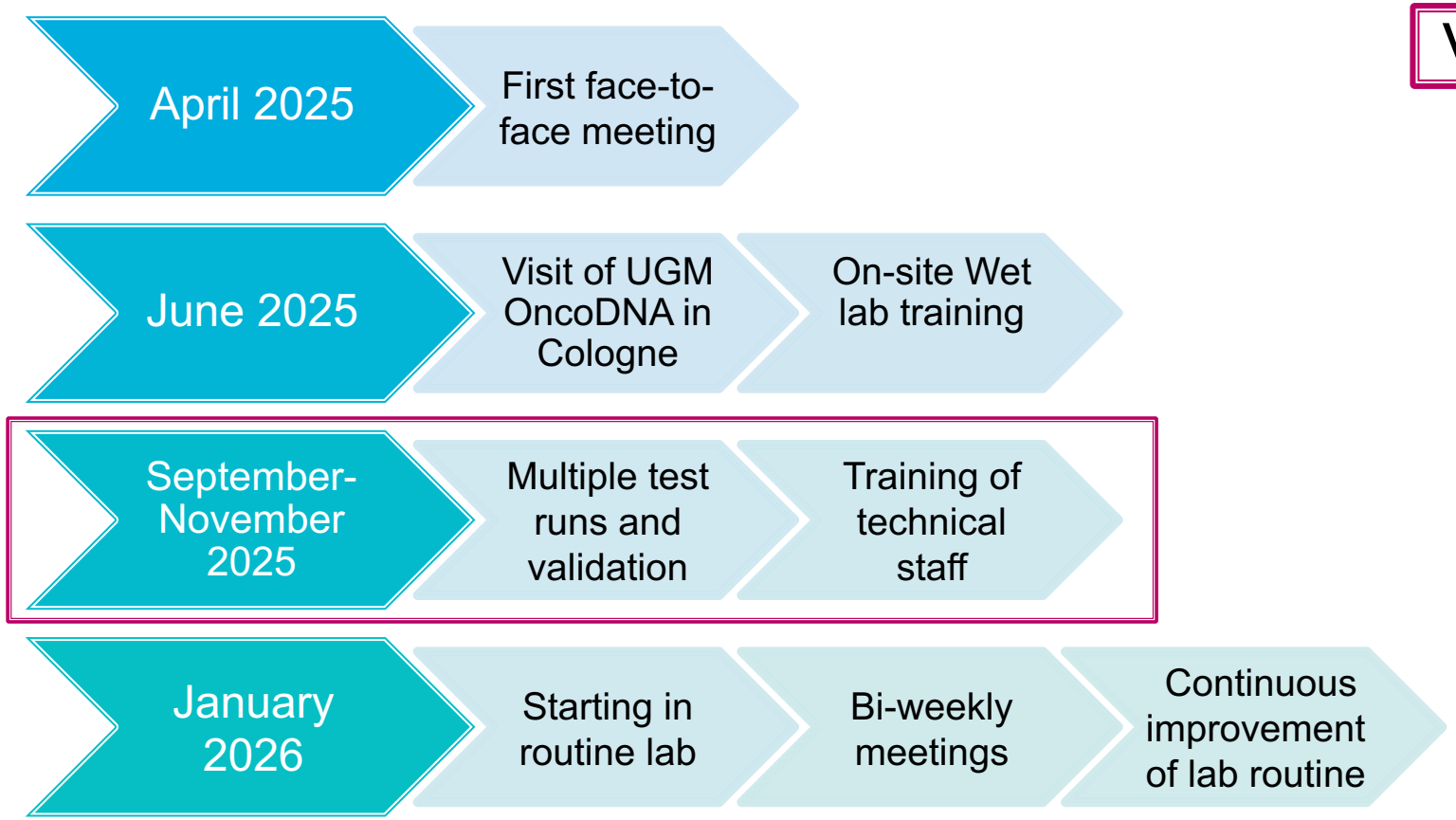
Validation and Training plan

Routine plan

Improvements

Automatization

# Validation and Training plan

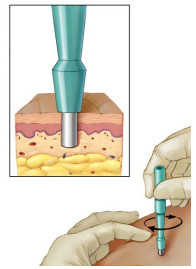



## Validation and Training plan

- Finding the right QC parameter
- In-house Validation
- Training technical staff
- Adapting protocol to the routine workflow

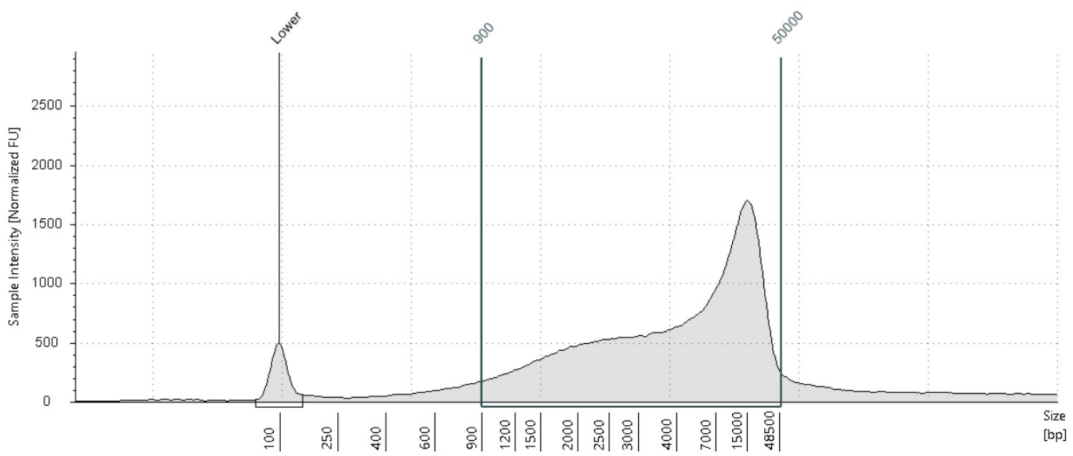
# In-house Validation

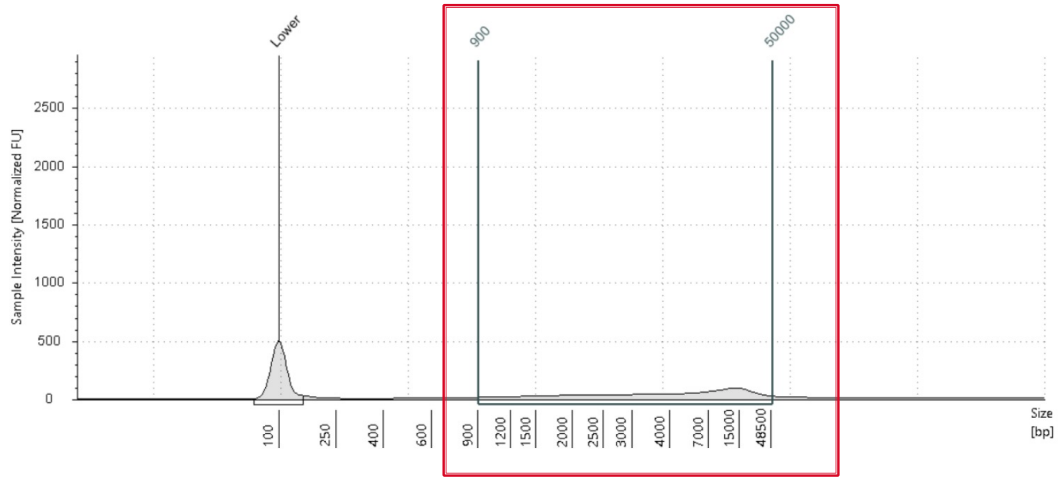
1. **QC performance** (defining minimum QC thresholds for library prep)



Overcoming challenge: poor quality of FFPE-tissue (especially punch biopsies)

→ Most samples do not meet OncoDNAs criteria for library prep




Aim: Analyze and evaluate as many samples as possible, including those of particularly poor quality

**Which internal QC parameters can we use?**

# In-house Validation

## 1. **QC performance** (defining minimum QC thresholds for library prep)

### DNA-QC

n=91

| | Conc. Sample [ng/µl] | DV900 [%] | Conc. Library [ng/µl] | Mean Coverage [X] |
|---|---|---|---|---|
| Conc. Sample [ng/µl] | 1 | 0,43 | 0,41 | 0,33 |
| DV900 [%] | 0,43 | 1 | 0,78 | 0,58 |
| Conc. Library [ng/µl] | 0,41 | 0,78 | 1 | 0,62 |
| Mean Coverage [X] | 0,33 | 0,58 | 0,62 | 1 |

very strong correlation

no correlation

### RNA-QC

n=36

| | Conc. Sample [ng/µl] | DV200 [%] | Conc. Library [ng/µl] |
|---|---|---|---|
| Conc. Sample [ng/µl] | 1 | 0,72 | 0,57 |
| DV200 [%] | 0,72 | 1 | 0,66 |
| Conc. Library [ng/µl] | 0,57 | 0,66 | 1 |

very strong correlation

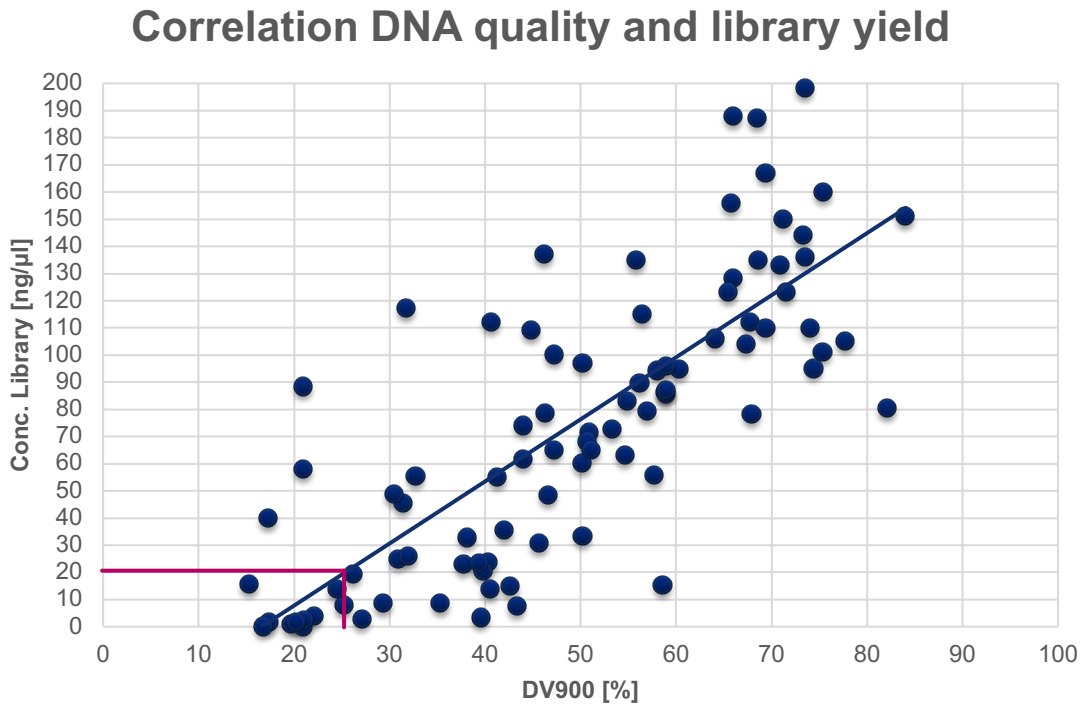
no correlation

Strong correlation between DV900/DV200 and library concentration

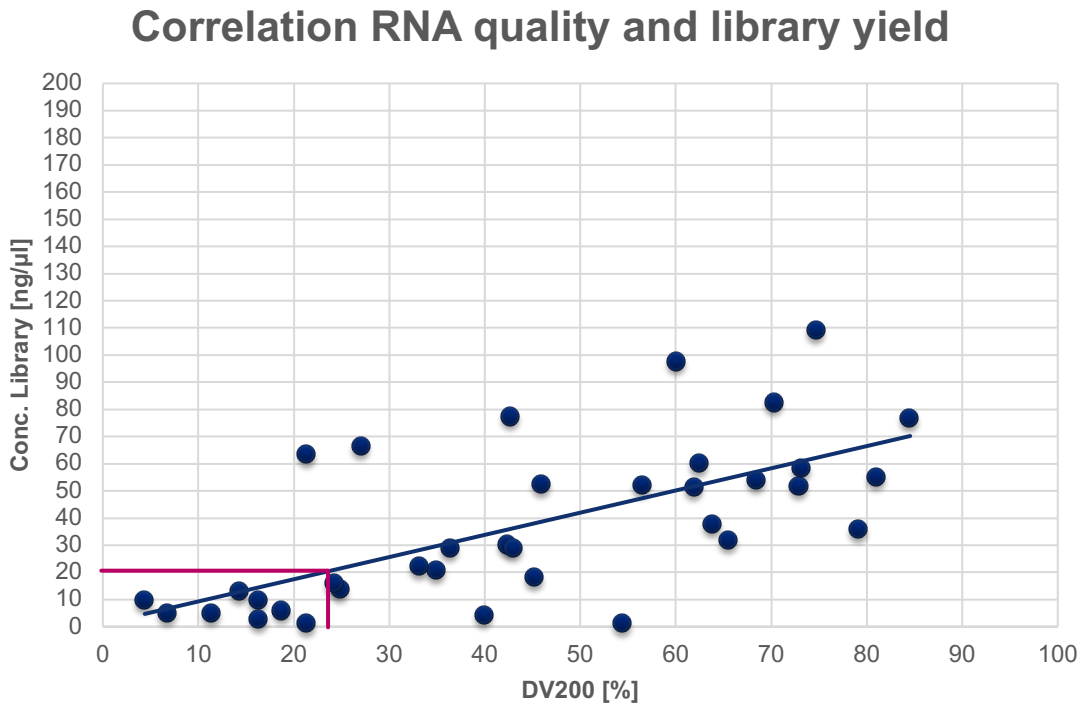
**DV900 and DV200 as critical quality indicators for sample selection**

# In-house Validation

## 1. **QC performance** (defining minimum QC thresholds for library prep)




DV900 > 25-30%




DV200 > 25-30%

**Use of DV900/DV200 as internal Quality-Based Exclusion Criterion**

# In-house Validation

## 2. Analytical performance (defining accuracy, sensitivity and specificity)

Reference NGS panels:
- Focus Research Assay (TF)
- Classic (AmoyDx)
- HRD (AmoyDx)
- HRR (AmoyDx)
- TSO500 (Illumina)

**DNA**

Mutations

| | | OncoDEEP® | |
|---|---|---|---|
| | | *WT* | *Mut* |
| ref. panel | *WT* | 4 | 0 |
| | *Mut* | 0 | 47 |

100 % accuracy
100 % sensitivity
100 % specificity

**RNA**

Fusions

| | | OncoDEEP® | |
|---|---|---|---|
| | | *No Fus* | *Fusion* |
| ref. panel | *No Fus* | 20 | 0 |
| | *Fusion* | 0 | 5 |

100 % accuracy
100 % sensitivity
100 % specificity

**Very good performance for mutations and fusions**

# In-house Validation

## 2. Analytical performance (defining accuracy, sensitivity and specificity)

**Genomic Biomarkers**

### MSI

| | | OncoDEEP® | |
|---|---|---|---|
| | | *MSS* | *MSI* |
| ref. panel | *MSS* | 5 | 0 |
| | *MSI* | 1 | 6 |

92 % accuracy
86 % sensitivity
100 % specificity

- Discrepancies between OncoDEEP® and reference methods
- Some cases (validation and routine) classified as MSS by OncoDEEP® but MSI by reference

### TMB

| | | OncoDEEP® | |
|---|---|---|---|
| | | *TMB low* | *TMB high* |
| ref. panel | *TMB low* | 3 | 0 |
| | *TMB high* | 1 | 0 |

75 % accuracy

- Limited number of samples available to date (customer demand increasing)
- **One false negative case** identified, likely attributable to **borderline TMB** score in both methods

### HRD

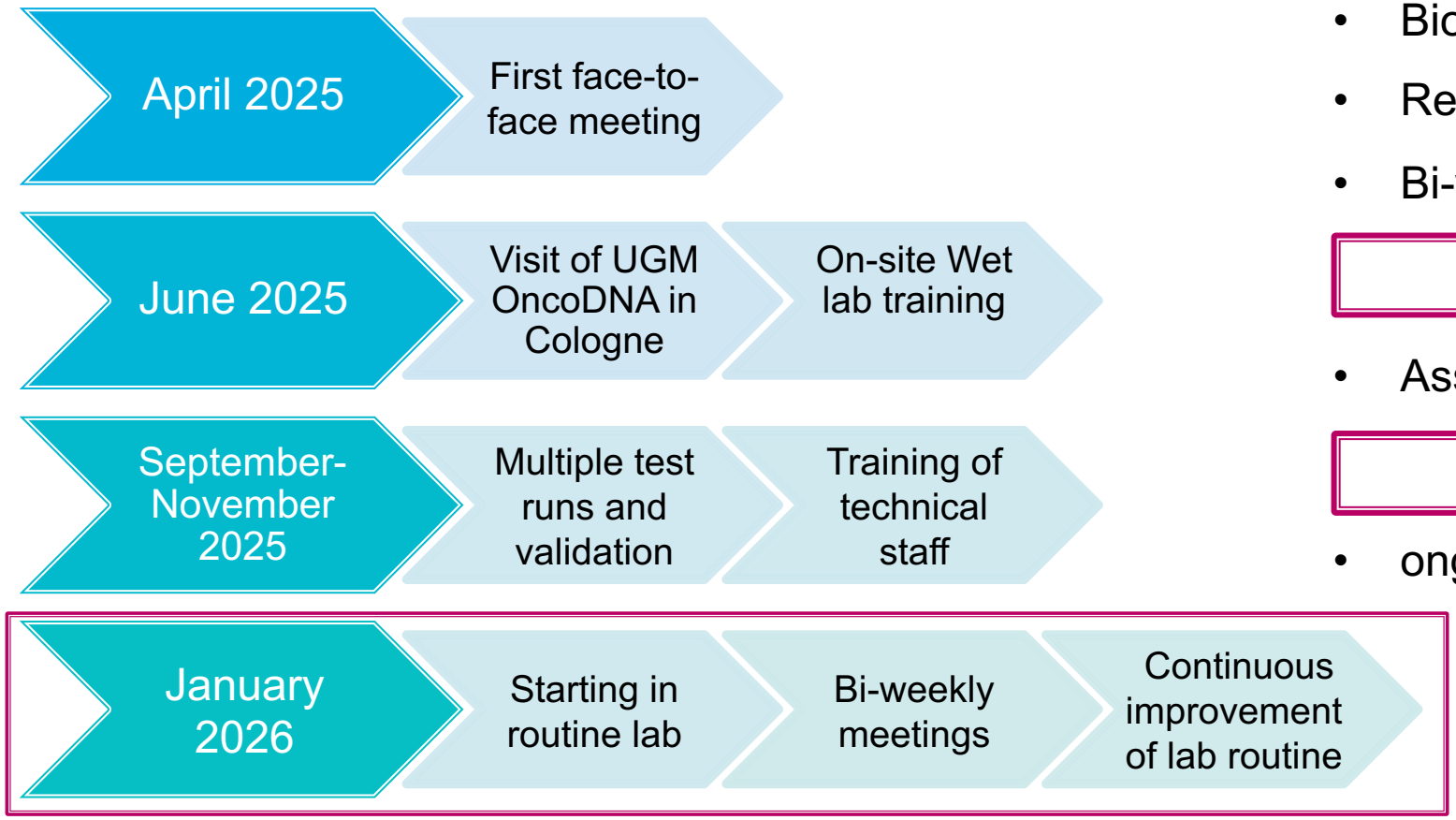
| | | OncoDEEP® | |
|---|---|---|---|
| | | *HRD neg* | *HRD pos* |
| ref. panel | *HRD neg* | 1 | 0 |
| | *HRD pos* | 2 | 7 |

80 % accuracy
78 % sensitivity
100 % specificity

- **Two false negative cases identified**
- One associated with a VuS BRCA2 variant → not classified as relevant for HRD by OncoKDM
- One associated with a **borderline GS score**

**More samples need to be tested**

# Routine plan




## Routine plan

- Experienced technical staff
- Biologist for analysis and interpretation trained
- Reporting documents changed
- Bi-weekly meeting with OncoDNA

## Improvements

- Assistance for an easier workflow

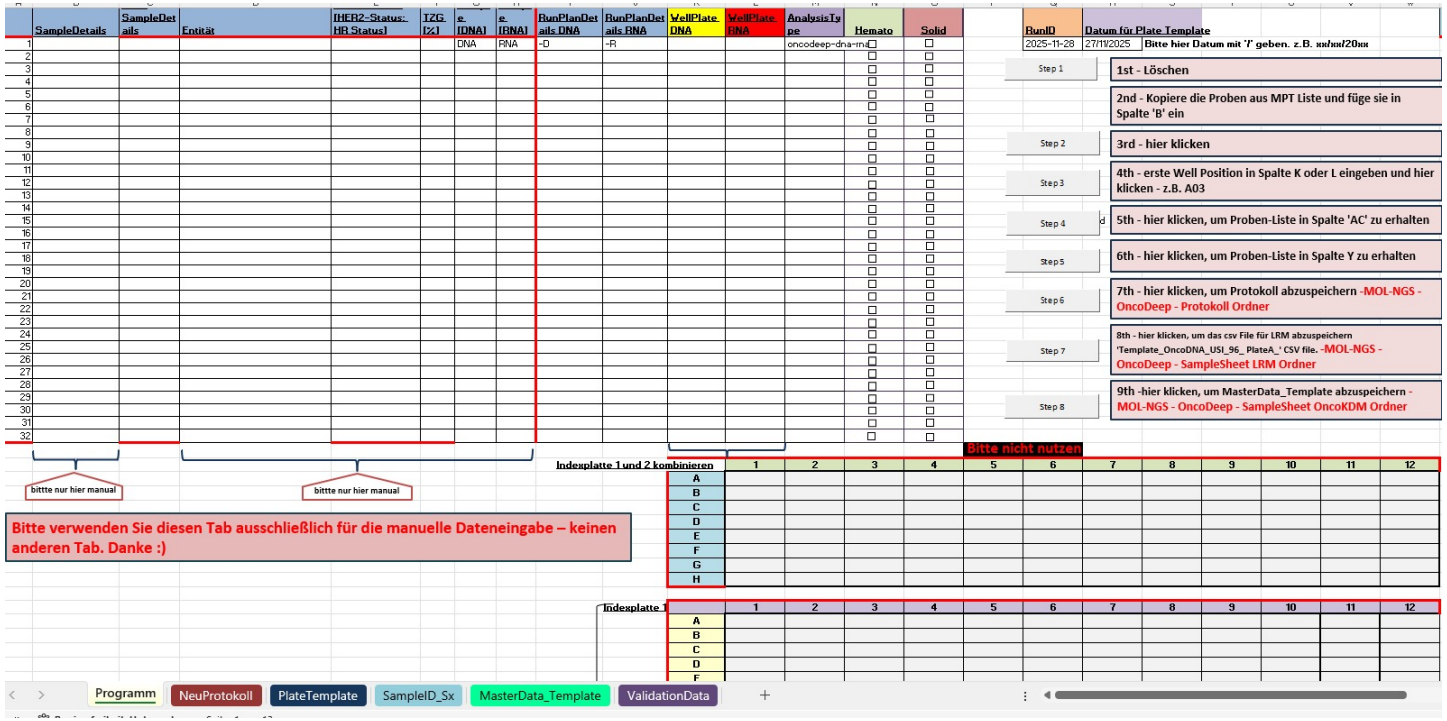
## Automatization

- ongoing

# Improving Lab-Management

**Issues**:
Missing LIMS for Mol-Path
Difficulties with generating sample sheet for sequencing and master datasheet

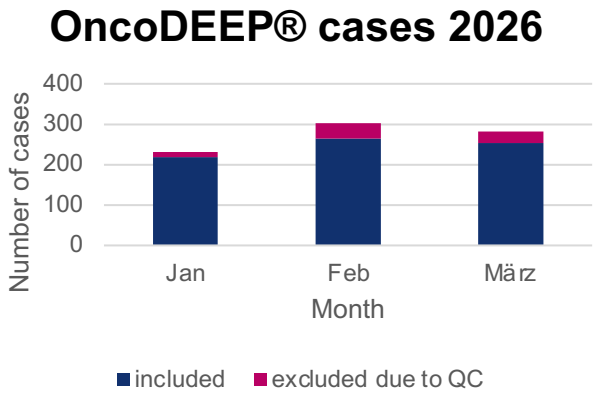
**Problem solving**:
Generating a program with Excel, helping the technicians to generate files



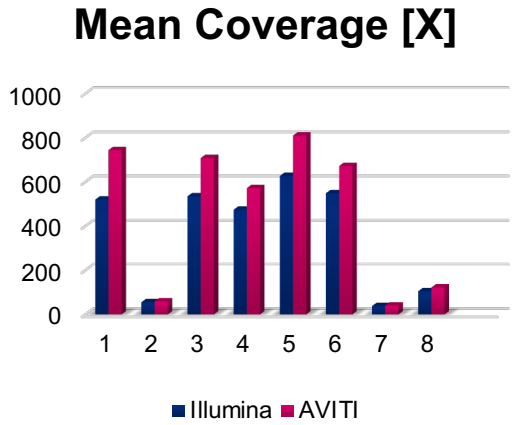
# Future Perspectives

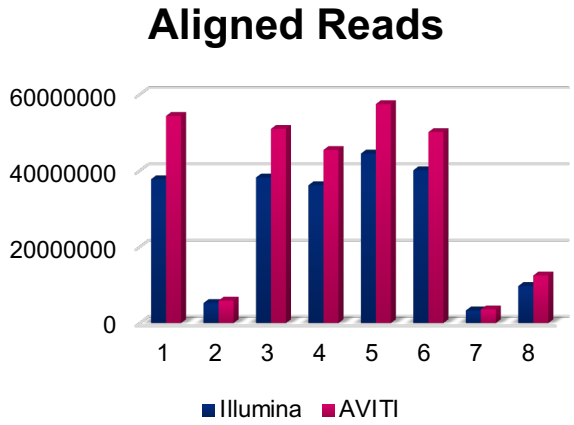
## More to come

→ Automatization (Hamilton)




→ Alternative sequencing platform (AVITI)

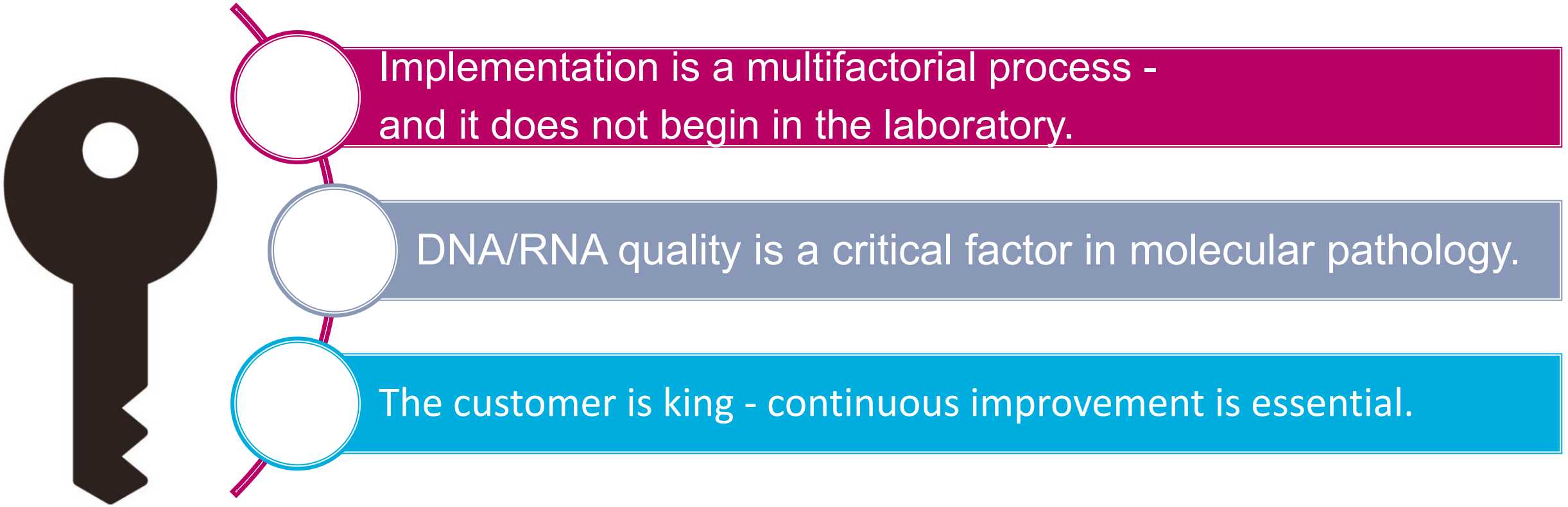



→ Testing additional panels

- OncoSELECT®
- Large RNA panel
- OncoXPLORE®

# Key Take Away Slide

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MVZ FÜR HISTOLOGIE, ZYTOLOGIE UND
MOLEKULARE DIAGNOSTIK TRIER GmbH

# Thank you

PATHOLOGIE TRIER
Histologie. Zytologie. Molekulare Diagnostik.

Dr. Marina Wierz
Dr. Norbert Arens
And all members of the MOL-Team

OncoDNA
THE CANCER THERANOSTIC COMPANY

Dr. Dan Brudzewsky
Dr. Jean Baptiste Mariaux
Dr. Jean-Francois Vanbellinghen