

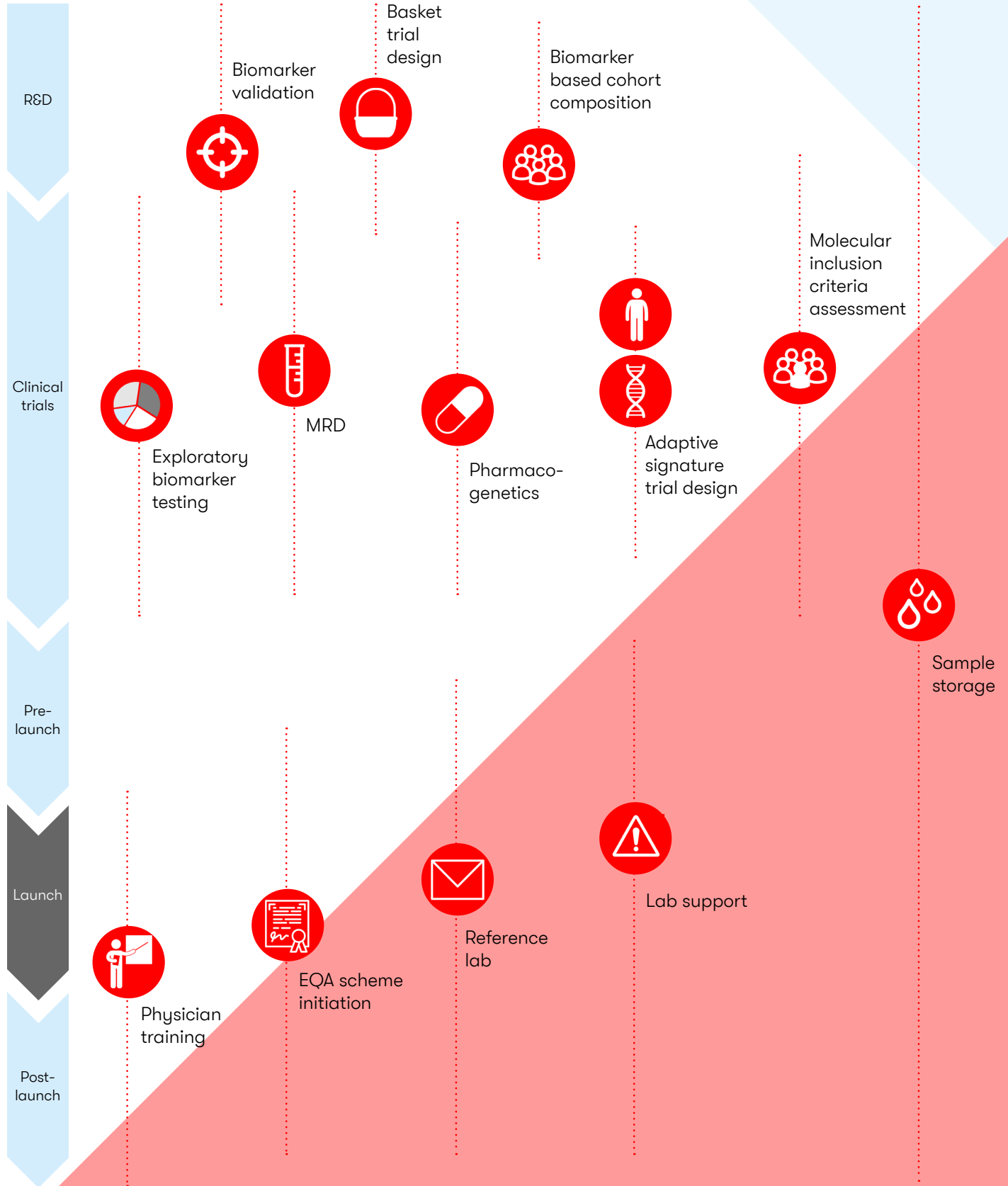
Pharma Services

Optimal diagnostics for clinical research.

MLL Dx GmbH in cooperation with
MLL Munich Leukemia Laboratory



Your partner for premium clinical research & diagnostics





Clinical lab services

MLL Munich Leukemia Laboratory

- Private clinical lab in Munich, Germany
 - Prof. Dr. med. Dr. phil. Torsten Haferlach
 - Prof. Dr. med. Claudia Haferlach
 - Prof. Dr. med. Wolfgang Kern
- 08/2005: 29 employees; 1200 m² lab space
- 05/2024: 340 employees; 7500 m² lab space
- Scientists: 109; technicians: 187; staff: 44
- Laboratory operations: 7 days workflow
- IVDR compliant, ISO 15189, ISO 17025, and CAP accreditation
- Reference laboratory for various collaborators (pharma)
- Research group & international cooperations

Diagnostics

Comprehensive diagnostic portfolio, e.g.

- Polymerase chain reaction-based methods (qPCR, dPCR, RT-PCR, Fragment length analysis)
- Next-generation sequencing (NGS):
 - targeted Panel, Whole-exome sequencing (WES),
 - Whole-genome sequencing (WGS), Whole-transcriptome sequencing (WTS)
- 10 color flow cytometry
- Cytogenetics (G-banding)
- Fluorescence in situ hybridization (FISH)
- Chromosome painting, incl. 24 color FISH
- Cytomorphology
- Cytochemistry
- Magnetic-activated cell sorting, CD138 (MACS)
- cell sorting
- single cell sequencing (10X Genomics certified service provider)
- sample storage
- assay development and qualification



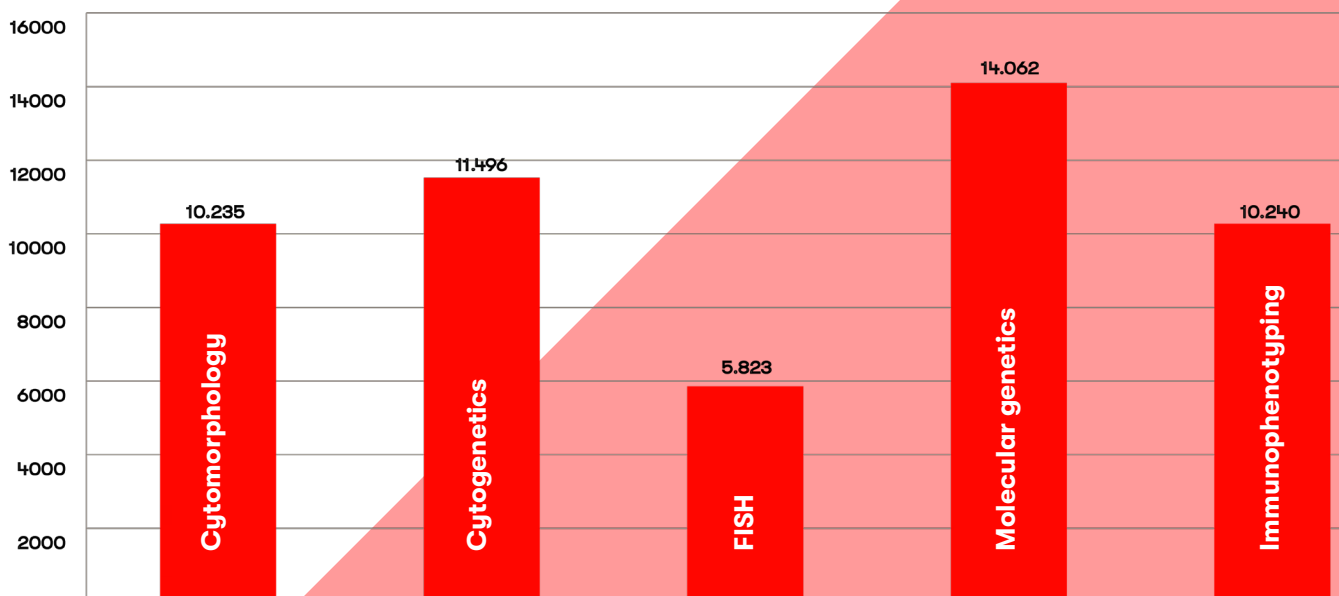
Clinical lab services

Turnaround time (TAT)

Methods	Required processing times
Cytomorphology, cytochemistry	2 hours to 1 day
Immunphenotyping	2 hours to 1 day
FISH	1 to 3 days
Sequencing	3 to 10 days
Quantitative PCR	1 to 5 days
PCR for detection of fusion genes	1 to 5 days
Cytogenetics	3 to 7 days
24-color FISH, incl. chromosome analysis	5 to 10 days

Our expertise

Samples in clinical trials at MLL



Number of samples per diagnostic method from 08/2005 - 05/2024.

Sum: 51,856 analyses for 22,489 samples; 2.3 methods per sample.



Clinical lab services

Clinical trial services - pre-launch

- **State-of-the art methods** in Cytogenetics, FISH, Cytomorphology, Immunophenotyping, Molecular Genetics and MRD
- **24/7/365** service available
- Clinical reports can be issued if required
- **MRD**
- **Scalable workflows** for all offered methods
- Assessing diagnostic **inclusion criteria**
- **Sample storage** systems (RT, 4°C, -20°C, -80°C, -160°C, viable cells) for subsequent analysis
- World-class **NGS** analyses (targeted Panel, WGS, WES, WTS) incl. bioinformatic result interpretation
- **AI** to integrate available information in one comprehensive analysis

Clinical trial services - post-launch

- **Reference/central lab service** with accredited state-of-the art methods in Cytogenetics, FISH, Cytomorphology, Immunophenotyping and Molecular Genetics, MRD
- **24/7/365** service available
- **Scalable workflows** for all offered methods
- **Short TATs** can be adopted to clinical needs
- Clinical reporting in English available
- Experienced in processing international routine samples
- Clinical reports meet all requirements of current guidelines and recommendations
- ISO 15189, ISO 17025 and CAP accreditation, 21 CFR part 11 compliant

Facts about clinical trials at MLL



63

clinical studies



22,489

analyzed clinical study samples



2.3

methods applied in average per sample

08/2005 - 05/2024



Medical and scientific affairs

Study team consultancy

- MLL experts to support developing an **overarching clinical diagnostics plan** allowing biomarker analyses across different clinical development phases and comparison of different leukemia/lymphoma entities
- MLL experts support designing the most **efficient diagnostics in clinical trials** – tailored design of test combinations for each clinical study/phase
- MLL experts to **advise** in all laboratory-related matters, e.g. appropriate technologies, test menus, biomarkers, optimal sampling time points, required sample types, MRD

Lab support program - pre- and post-launch

- Suggest, arrange and conduct **EQAs or ring studies**, incl. provision of appropriate and sufficient samples and the review of participants results
- Evaluate current diagnostic performance and provide helpful **feedback to labs**
- Perform webinars or workshops to **educate labs/physicians** on appropriate sample testing (on-site and/or virtual)
- Support labs in **validating assays** (on-site and/or virtual)
- Provide **test samples** (positive and negative controls)
- **On-site lab visits** to improve diagnostic workflows and ensure high quality diagnostics



Medical and scientific affairs

Educational knowledge transfer

Publications

At MLL the daily routine diagnostics along with the numerous scientific projects lead to continuous increases in the expertise of hematological malignancies. Our goal is to make this knowledge available to physicians and scientists.

MLL Academy

A 3-days workshop at MLL in Munich:

- Respective MLL-experts for each topic as presenters
- Practical and theoretical interactive sessions
- All lectures held in modern MLL seminar rooms
- Practical demonstrations and trainings in optimally equipped MLL laboratories
- Variety of hemato-oncological entities and latest technical developments covered



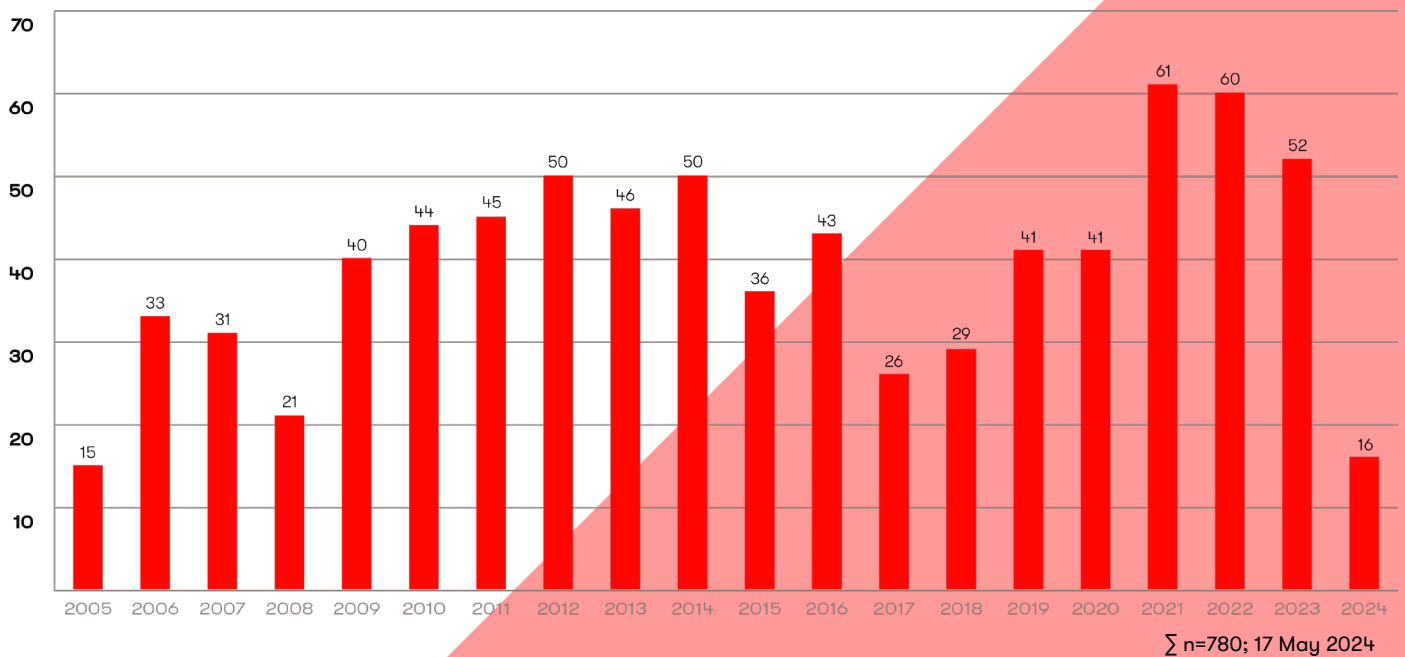
Biomarker research

Our research expertise

MLL's research focuses on developing diagnostics and therapeutic options for patients with hematological malignancies. Through both in-house research and worldwide collaborations, we strive to advance and support research and knowledge. MLL's prospective study BELUGA (Better Leukemia Diagnostics Through AI; Clinicaltrials.gov, NCT04466059) investigates AI-guided diagnostics of cytomorphology and immunophenotyping.

MLL applies latest technologies like AI and NGS (panel, WGS, WTS, scRNAseq) in its research projects in order to understand biological disease complexity and support precision medicine.

Publications per Year

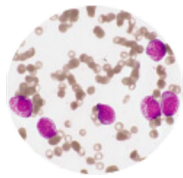




Biomarker research

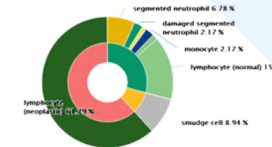
Our research expertise

Artificial intelligence - AI-tools developed by MLL



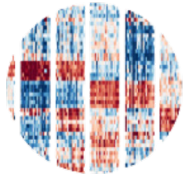
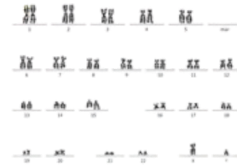
Cytomorphology

Fully automated blood smear analysis & cell classification



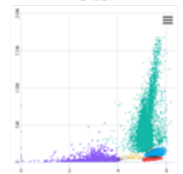
Cytogenetics

Fully automated metaphase detection & karyotyping



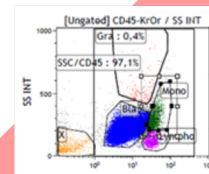
Molecular genetics

Fully automated WGS data analysis & interpretation






Immunophenotyping

Fully automated gating & phenotyping



Data Security

-  ISO 15189, ISO 17025, CAP, CRF 21 part 11
-  EU general data protection regulation (ISO 27001, ISO 27017, ISO 27018)
-  Cloud Computing Compliance Controls Catalogue

Clinical biomarker research

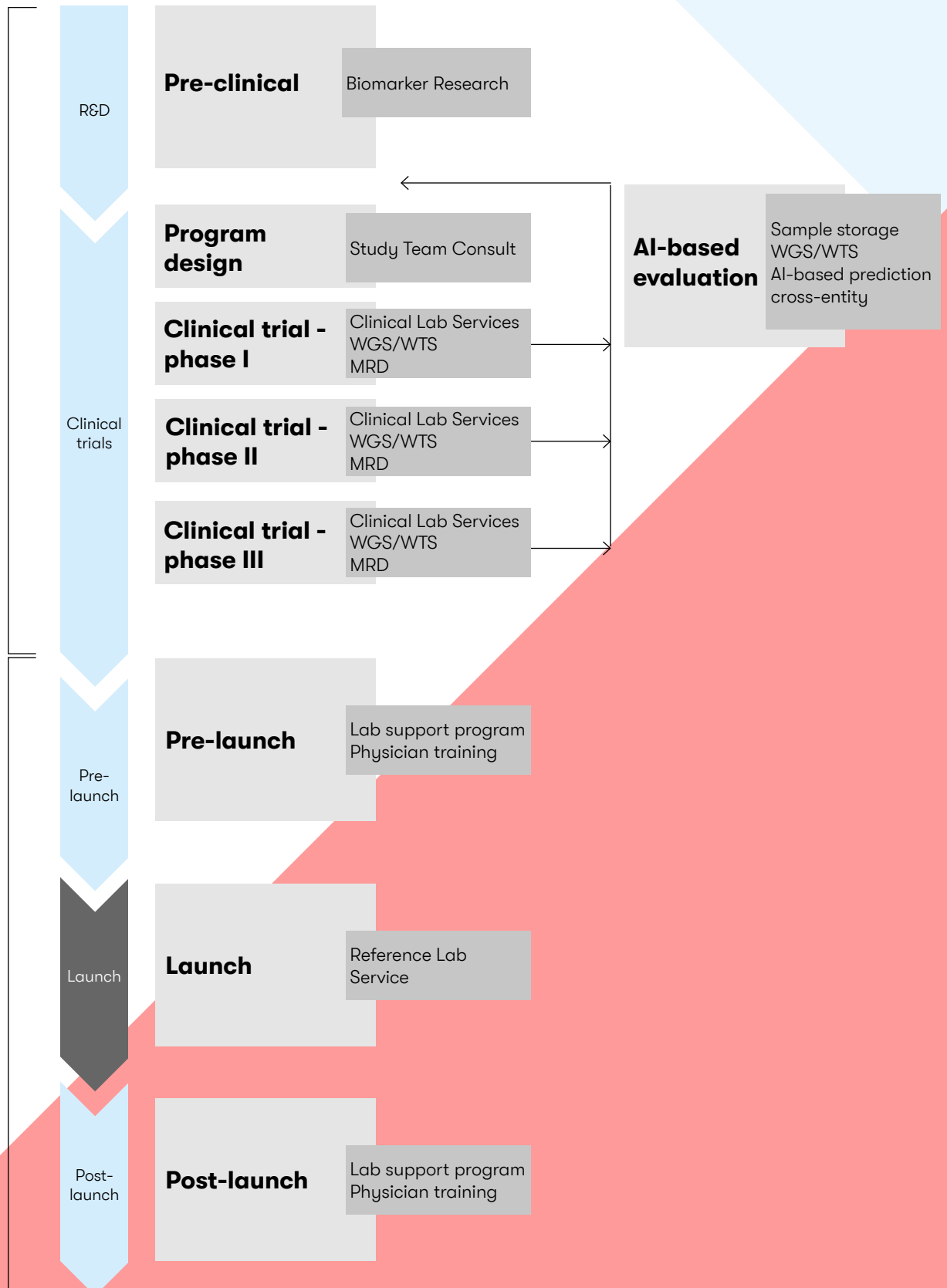
- **Biomarker analysis**, incl. standard diagnostic workup according to current guidelines and recommendations
- Anonymized routine diagnostic data readily available from over **700k hemato-oncology patients**
- About 5k patient samples with **matched WGS and WTS** data available
- **Diagnosis vs MRD**
- **Panel, WES, WGS, WTS**
- Integration of different methods (Cytogenetics, FISH, Cytomorphology, Immunophenotyping and Molecular Genetics) to **distinguish patient groups** and to apply current classification and prognostication systems
- AI to identify alterations **predicting treatment response**
- **Screen additional hematological entities** for similar/identical alterations
- Support with disease-agnostic biomarker-dependent study designs



Modular and flexible to enable optimal diagnostics for clinical trials and programs

MLL Dx Services to support all clinical trials and Biomarker-related activities in hemato-oncology

MLL Dx Services to support therapies with defined diagnostic requirements





MLL Dx GmbH
Max-Lebsche-Platz 31
81377 Munich
Germany

info@mll.com
T +49 89 99017-0
F +49 89 99017-111

mll.com/en/pharma