eurobio gendx

Companion Diagnostic solutions with GenDx

Your partner from start to finish

Expert molecular diagnostic solutions
for the analysis of HLA, KIR, MICA/MICB,
Chimerism monitoring, and more

GENDX: YOUR COMPANION DIAGNOSTIC PARTNER FROM START TO FINISH

GenDx, part of the Eurobio Scientific group, was founded in 2005 and has grown into a global leader in molecular diagnostics. With a strong presence in Europe and the USA, we pioneered transplantation diagnostics with NGS-based HLA typing and expanded into Chimerism Monitoring. Today, GenDx's expertise extends to multiple gene families, including KIR, MICA/MICB, and beyond.

In May 2022, GenDx became the first company in the field to obtain IVDR (in vitro medical device regulation) certification for both its HLA typing reagents and analysis software. Our NGSengine® software is recognized as the gold standard for NGS HLA typing.

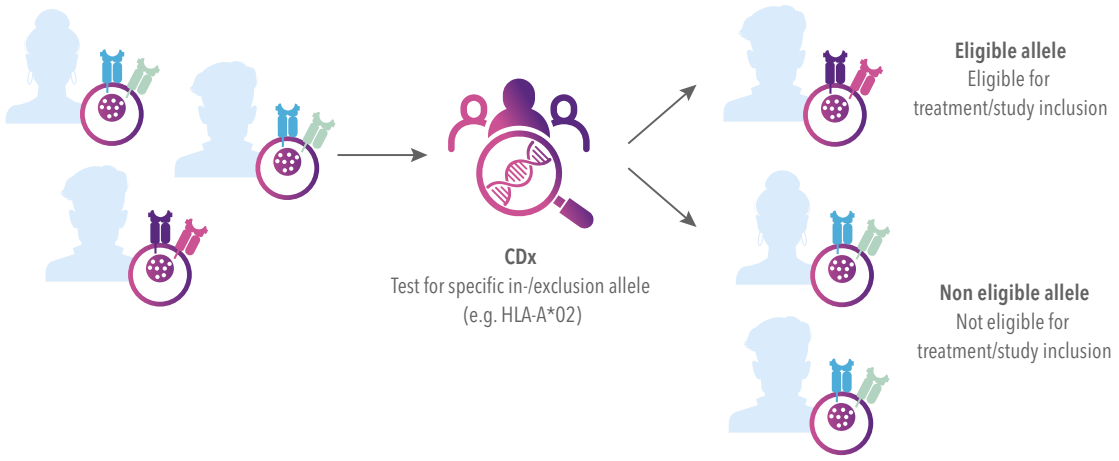
Why collaborate with us?

With all expertise in-house, from R&D to regulatory affairs, we ensure a fast, seamless, and efficient tailor-made Companion Diagnostics (CDx) development process.

- **CE-marked molecular diagnostics under IVDR** – NGS-based HLA typing reagents and analysis software
- **Rapid development timeline** – From CE-marked legacy device to tailor-made device for clinical performance study in 6-9 months
- **Broad assay development capabilities** – For analysis of complex genes, such as HLA, KIR, MICA/MICB, Chimerism Monitoring and more
- **End-to-end expertise** – Including assay development, manufacturing, supply chain control and regulatory support
- **Full-service Clinical Performance Study CDx support** – Facilitating bridging studies and interventional studies from idea to CDx
- **Proven regulatory experience** – Europe and USA study approvals, with global expansion capability
- **Flexible, collaborative approach** – Tailored solutions to meet your CDx needs
- **Strong global network** – Supporting clinical studies and regulatory submissions

TAILORED CDx FOR PRECISION MEDICINE

From concept to clinical implementation



Are you developing a therapy that requires precise patient selection? A CDx solution can enable:

- **Targeted patient identification** – Select patients most likely to benefit from your therapy
- **Risk stratification** – Identify individuals at higher risk for serious adverse reactions
- **Therapy monitoring** – Track treatment response for optimized safety and efficacy

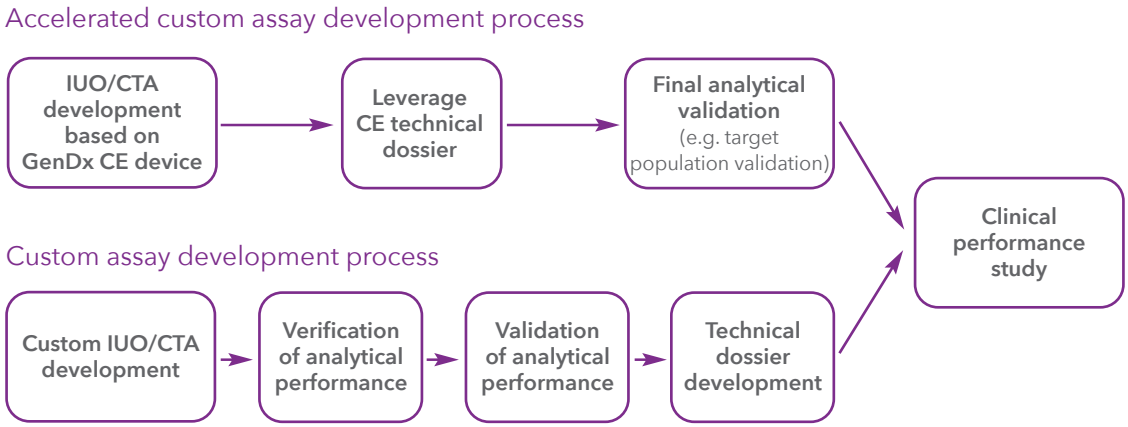
With deep expertise in molecular diagnostics and regulatory compliance, we can develop customized CDx solutions tailored to your therapeutic strategy.

Let's shape the future of precision medicine together!

FLEXIBLE CDx DEVELOPMENT, CUSTOMIZED TO YOUR NEEDS

There are different options for the development of the clinical trial assay (CTA) or CDx. If the **development of the assay starts from a currently CE-marked device under IVDR**, such as our single- or multiplex HLA typing assays, we can partially leverage the technical dossier of this device. This will allow for an **accelerated custom assay development** process of your IUO (Investigational Use Only) or CTA, which can be done in 6 to 9 months (depending on project-specific factors).

Alternatively, we can offer **custom assay development** for new targets. Development can start from one of our RUO devices if it covers the target of interest. We can also develop assays for other gene families. As this development track will not be able to leverage the IVDR technical dossier, a longer development process needs to be considered. Nevertheless, our experience with IVD development and our strong regulatory expertise will ascertain that requirements will be met.



The IUO/CTA can be clinically validated through either in an **interventional study** or a bridging study. The design of a interventional clinical study will be in mutual agreement with the pharmacological sponsor, to align with the needs and requirements of the clinical trial. If the pharmacological clinical trial has already been conducted but you are looking for a state-of-the-art CDx, GenDx can develop the device and execute the required bridging study. Through our strong network of collaborators, GenDx can assume **full responsibility for the bridging study** and ascertain that all regulatory requirements are satisfied.

ADVANTAGES OF NGS OVER SANGER-BASED HLA TYPING

GenDx offers both Sanger and Next-generation-based sequencing (NGS) solutions. While Sanger sequencing has long been a trusted method, NGS provides key benefits that make it future-proof for modern molecular diagnostics.

Feature	Sanger Sequencing	Next-Generation Sequencing (NGS)
Gene coverage	Partial gene coverage	Full gene coverage
Typing accuracy	Ambiguities may require additional sequencing rounds or add-on products	Unambiguous results–no extra sequencing needed
Hands-on time	High; labor-intensive	Minimal; streamlined workflow
Scalability	Limited scalability	Scalable for high-throughput applications
Multiplexing	Single-gene analysis per reaction	Simultaneous analysis of multiple genes
Technology	Dated technology	Future-proof and adaptable

With GenDx NGS solutions, you benefit from a platform-agnostic approach, meaning our reagents and software can seamlessly integrate with various NGS platforms and adapt to future sequencing technologies.

HARNESSING OUR EXPERTISE IN DEVELOPING MOLECULAR DIAGNOSTICS

Our broad portfolio of IVD products and analysis techniques enables the **precise** analysis of complex genes such as HLA, KIR, MICA/MICB, and chimerism monitoring. We provide state-of-the-art molecular diagnostics based on:

- **Next-Generation Sequencing (NGS)**
  - long- and short-read
  - PCR-based or capture-based enrichment
  - library preparation
  - platform independent analysis software
- **Sanger Sequencing**
  - Reagents and analysis software for high-resolution Sanger-based HLA typing
- **qPCR and dPCR**
  - cfDNA
  - Reagents and software analysis for cfDNA monitoring
  - gDNA analysis & software
  - Reagents and software analysis for gDNA based chimerism monitoring

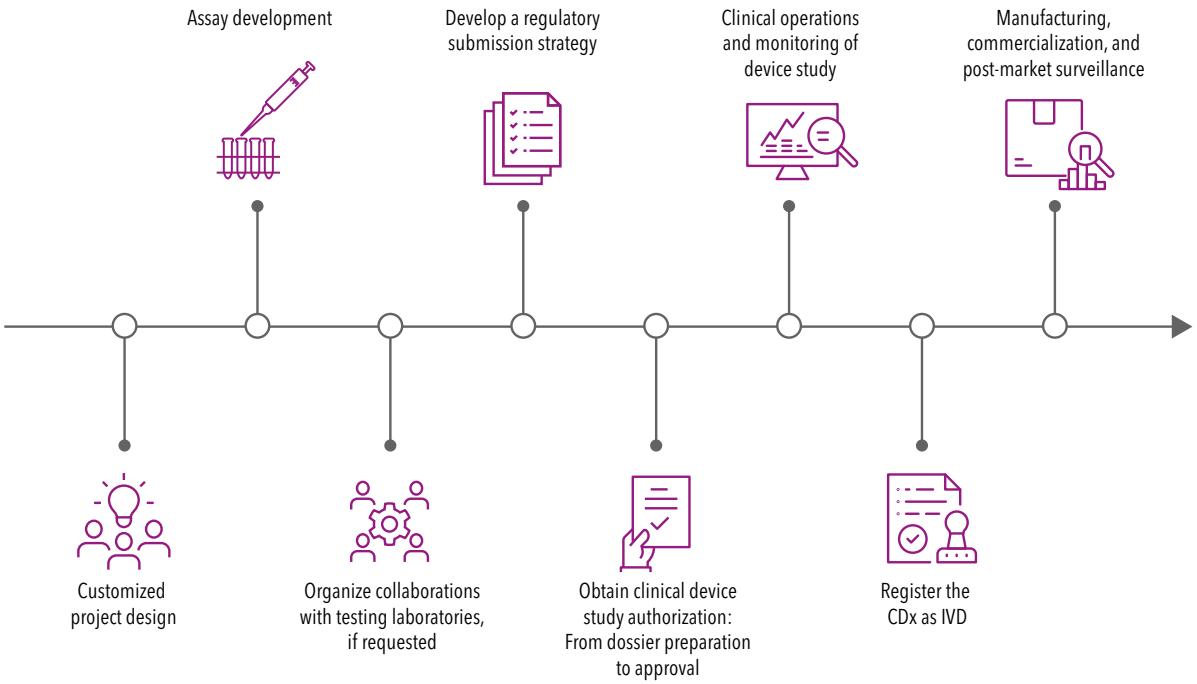
By leveraging our existing CE-marked devices, we can develop your clinical trial assay in as little as 6–9 months, streamlining the path to regulatory approval. You can find an overview of our CE-marked products under IVDR in the list below. To explore our RUO and prototype devices, visit www.GenDx.com or contact us at CDx@gendx.com.

Available products

- CE-marked reagents and software for single- or multiplexed analysis of 11 HLA loci
  - Single locus amplification of HLA-A, -B, -C, -DRB1, DRB3, -DRB4, -DRB5, -DQB1, -DQA1, -DPB1, and -DPA1 (NGSgo®-AmpX v2/AmpX v3)
  - Multiplex amplification of 6 loci (HLA-A, -B, -C, -DRB1, -DQB1, and -DPB1) (NGSgo®-MX6-1)
  - Multiplex amplification of 11 loci (HLA-A, -B, -C, -DRB1, -DQB1 and -DPB1, DRB3/4/5, DQA1, and DPA1) (NGSgo®-MX11-3)
  - Library preparation and indexing reagents for sequencing on Illumina platforms (NGSgo® Library Full Kit)
  - Analysis software for HLA typing (NGSengine®)
- RUO reagents and software for analysis of KIR and MICA/MICB and chimerism monitoring
- Continued development of molecular diagnostics prototypes across additional gene families, leveraging diverse sequencing platforms and enrichment strategies

FROM IDEA TO CDx

Our dedicated project team will work closely with you to ensure that **every aspect of the project aligns with your specific requirements**. For every project, a cooperatively developed project design will be the basis to go from idea to CDx, as depicted below. Based on the requirements for your project, GenDx can take responsibility for each of these steps and/or support the entire process.



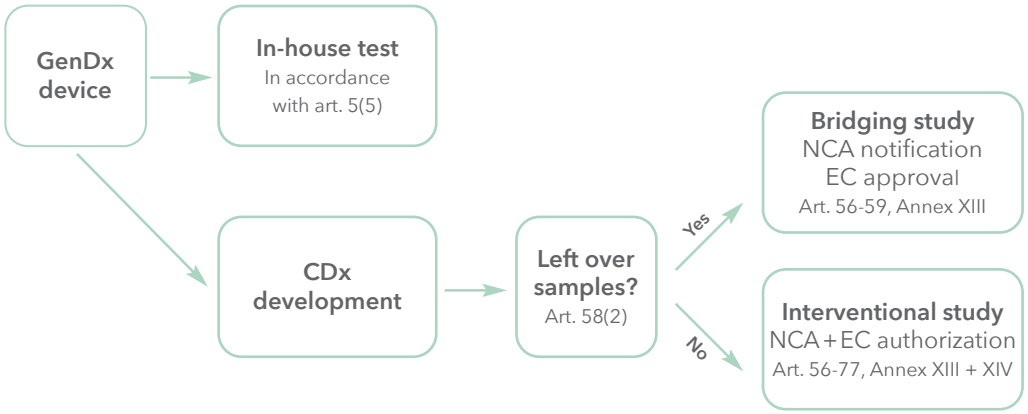
EXPERIENCE IN NAVIGATING THE REGULATORY LANDSCAPE

GenDx has a proven track record in obtaining authorization for Companion Diagnostics clinical performance studies performance studies in Europe and USA. We manage the application process for study approvals and facilitate authorization across global territories.

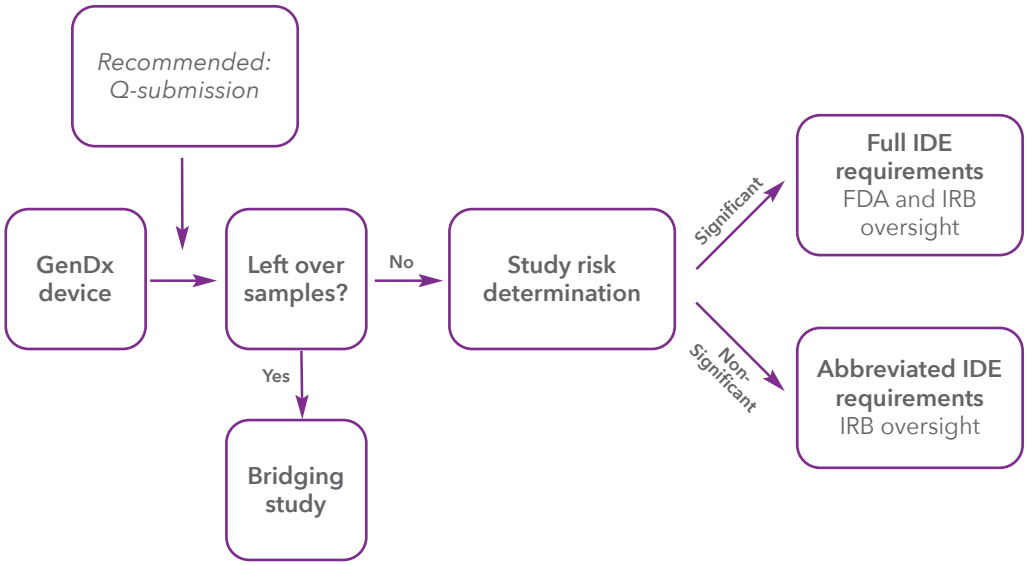
We offer complete regulatory support and can take full responsibility for the regulatory requirements, from dossier preparation to study close-out. We can offer among others:

- **Q-submission process**: Early engagement with FDA to request specific guidance to support the formal application for the clinical device study and Study Risk Determination.
- **Interventional clinical performance studies**: Parallel submission and execution of the clinical trial and clinical performance study to streamline study authorization timelines.
- **Clinical bridging studies**: Investigation of left over specimens from your clinical trial using a tailor-made CDx, allowing retrospective validation.

EU (IVDR, art. 56 - 77)



USA (FDA under 21 CFR 812)



The process of obtaining study authorization following IVDR or FDA regulations, is depicted in the simplified diagrams above, and depends on, among others:

- **Preferred type of study**:
  - Interventional or retrospective clinical performance study
- **Study risk and subject safety**:
  - In our experience, the study risk, according to the FDA, using our devices is often considered non-significant
- **Regulatory requirements by territory**:
  - Applicable regulation, such as IVDR in the EU or IDE in the USA.
  - Requirements and review process of ethics committees (EC) and national competent authorities (NCA)

If you are interested in learning more about study authorization processes, review timelines and how GenDx can support and facilitate your project, please contact us at CDx@gendx.com.

What our partners say about us

"At ARC, we are proud to partner with like-minded CDx companies, committed to kinder patient treatments. Our experience with the entire team at GenDx has been collaborative from day 1 taking every opportunity to listen and learn. GenDx has demonstrated a clear focus in delivering solutions while thoughtfully navigating the complex regulatory landscape with care and attention."

Heather Taylor, CCO, ARC Regulatory Ltd

INTERESTED IN LEARNING MORE?

CONTACT US

Not sure if you need a CDx for your clinical trial, or when to incorporate one?
Want to know more about what we can offer?
Reach out to CDx@gendx.com to learn how we can help!

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