



ZKRD Zentrales
Knochenmarkspender-
Register Deutschland

ANNUAL REPORT 2025

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“The highest form of responsibility is responsibility for another.”

– Dietrich Bonhoeffer

Together, we bring hope.
Together, we save lives.



In the world of blood stem cell donation, everyone has a profound responsibility. In this regard, responsibility is no abstract term – it is rooted in our daily activities. It begins with an individual’s decision to register as a voluntary stem cell donor, continues in the meticulous efforts of those working at the institutions involved, and extends far beyond transplantation. Within our network, responsibility is not only a moral obligation but also a principle reflected in everything we do. We must make decisions, shape processes and minimize risks while acting quickly when it matters. We carry this responsibility for people who hope for a second chance and for those who are willing to help others through their donation – and we share the responsibility together.

Not only do numbers count, but also the pathways people follow – with one another, for others, for a life that would be impossible without these concerted efforts. In 2025, we saw yet again just how much the success of blood stem cell donations depends on a complex set of interrelated factors: people, organizations working together across the globe, a robust medical supply chain, transport logistics, and the willingness of individuals to assume responsibility across borders.

That this responsibility also has a history became clear in March 2025, when Dr. Carlheinz Müller, the former Managing Director of the ZKRD, was honored at the International Donor Registry Conference (IDRC) with an invitation to deliver the Shirley Nolan Lecture.

We wish to thank him, everyone across this network who shares responsibility for this work, the donors for their willingness to save lives, and all colleagues and partners worldwide. After all, responsibility is demonstrated not by our words, but by our actions.

Dr. Peter Mein PD Dr. Joannis Mytilineos Volker Rump



Award for a lifetime achievement Shirley Nolan Lecture

A special moment in the history of our organization: In 2025, our former Managing Director Dr. Carlheinz Müller, who was instrumental in shaping the ZKRD from the outset, was invited to deliver the renowned Shirley Nolan Lecture at the International Donor Registry Conference (IDRC 2025) in Canada. This special recognition is not only a personal award, but also a great honor for a pioneer in blood stem cell donation on the international stage.

The Shirley Nolan Lecture is an honorary lecture within the international scientific community. It is used as a reminder of Shirley Nolan, who founded the world's first registry for unrelated stem cell donors – a milestone in the history of transplant medicine. The annual lecture honors people who have decisively shaped the worldwide search for donors through visionary thinking, tireless commitment and sustainable achievements.

Without a doubt, Carlheinz Müller is one of them. He made a pivotal contribution to the establishment of the central donor search system in Germany. Under his leadership, the ZKRD developed into a modern, globally networked organization. Early on, he recognized the need for global cooperation and worked intensively to build and expand the EMDIS network. Today, this electronic infrastructure forms the backbone of cross-border donor searches.

He also set standards in terms of technology. He and his team jointly developed the OptiMatch® system – an innovative computer-assisted method for donor selection that has now become one of the world's leading matching algorithms. Carlheinz Müller's guiding principle was maximum precision, to give patients around the world the best possible chance of a suitable transplant.

His untiring commitment to a faster and more efficient donor search has helped countless patients. The award of the Shirley Nolan Lecture therefore recognizes far more than just individual professional achievements. It marks a lifetime achievement that has influenced stem cell donation far beyond Germany's borders.

We warmly congratulate Carlheinz Müller on this special award and thank him wholeheartedly for everything he has done for the ZKRD and stem cell donation worldwide.



**Dr. Dr. Carlheinz Müller,
former Managing Director
of the ZKRD**



**Dr. Dr. Carlheinz Müller with
Henny Braund MBE, Chief Executive
at Anthony Nolan, during the
International Donor Registry
Conference (IDRC) in Québec,
Canada**



Interview with the ZKRD search team: A key role in the donor search

Donor-search processes are extremely complex and require close cooperation between all the partners involved. In this interview, the ZKRD search team offers insights into the key challenges and the collaborative efforts involved in finding a suitable donor for our patients.

Question: What makes the ZKRD search team so unique and why is its work so crucial to our patients?

Answer: We play a central role in the search for stem cell donors. Our task is to support the German search centers and international registries in their worldwide search for a suitable donor for patients. In doing so, we are the interface between all partners. Though search centers can largely work independently thanks to the extensive capabilities of our OptiMatch® matching software, questions and issues still arise that call for targeted solutions. This is where we step in. We quickly clarify these questions and find appropriate solutions, enabling the search process to continue without delay.

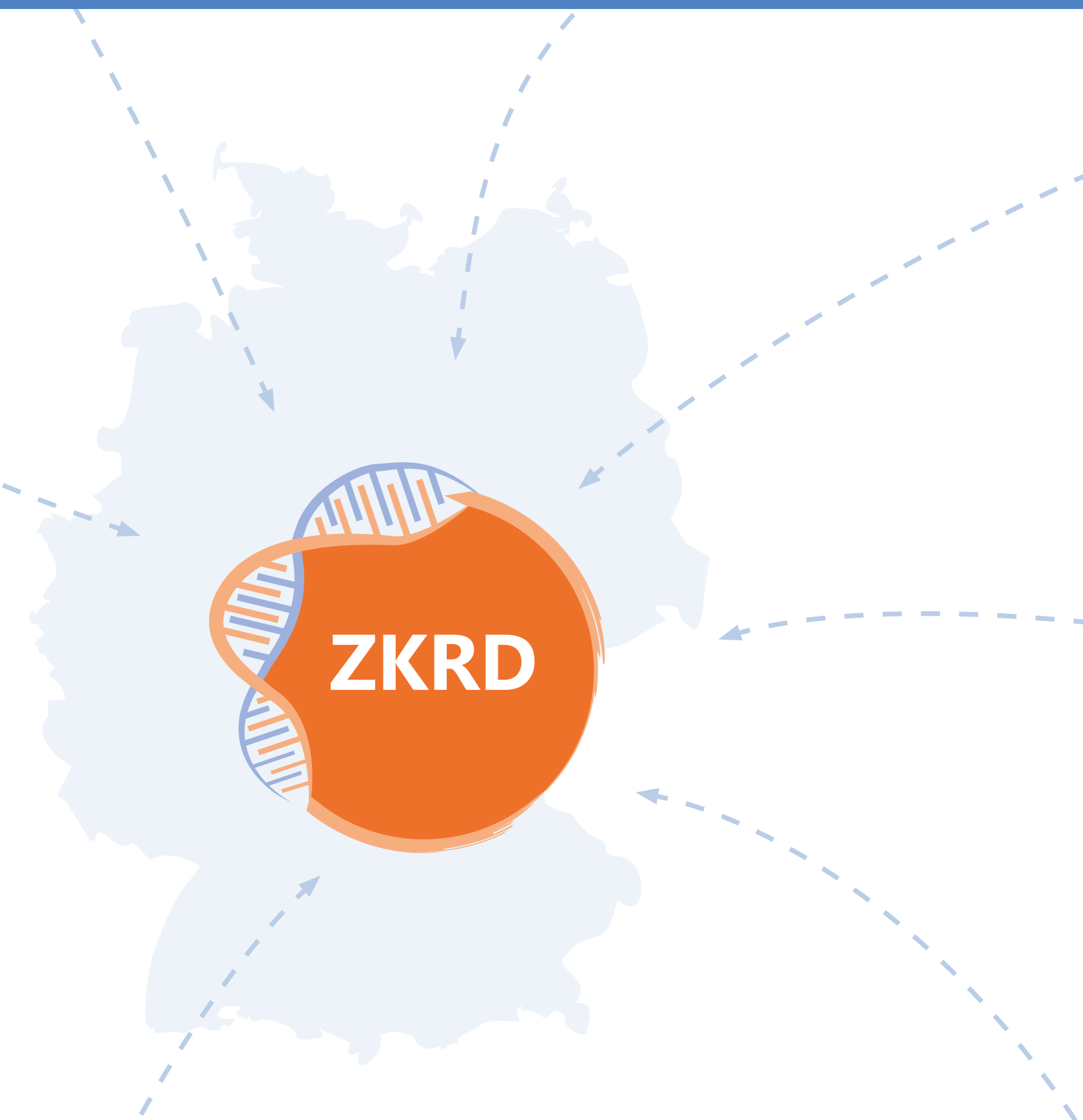
Question: How does the search team handle the questions and challenges?

Answer: A major part of our work is to carefully check the data transmitted for errors and inconsistencies. Quality assurance is always our focus. If we notice any anomalies, we work to resolve them immediately. We are often like detectives, tracing the causes of problems and solving cases. Sometimes the problem lies in incorrect search settings in the systems, sometimes a donor must be manually added to the match list. In such cases, we contact the relevant units to ensure that all the information is correct and complete. Since we are familiar with national and international regulations, we can swiftly make the necessary adjustments – always putting donor protection and data quality first.

Question: How does the ZKRD team ensure smooth collaboration with its partners, both nationally and internationally?

Answer: The ZKRD team plays an important role as the central point of contact for all partners in the entire process of communication and coordination of a donor search. This means that national and international partners can rely on the ZKRD to coordinate and clarify any questions and do not have to contact numerous institutions themselves. Without the ZKRD, each partner would have to approach the various institutions and countries individually with any questions or issues – often having to take numerous different systems, processes and regulations into account. We coordinate these activities, thus enabling everyone involved to concentrate on their core tasks. At the same time, we ensure that the search process is efficient and smooth by collating all the information and handling communication with the relevant units.

“Without the ZKRD, each partner would have to approach the different institutions and countries individually with any questions or issues...”



3 Interview with the ZKRD search team: A key role in the donor search

Question: How many steps are involved in the search for a suitable donor at the ZKRD, and what role does the search team play?

Answer: From receipt of the search documents to completion of the search, several steps are required, each of which is further broken down into sub-steps. The effort varies depending on the degree of difficulty and source of the search request. Some searches can be completed quickly, while others involve increased manual input and additional steps due to more complex requirements or extraordinary circumstances. For example, the search for a German patient can be rapid and straightforward, whereas other cases may take twice as many steps to complete. In 2025, 4,448 searches were initiated for German patients and 8,308 for patients worldwide.

More than 50 new search requests are added to the ongoing searches every day and processed by the ZKRD search team on the day they are received. Missing medical information or errors such as transposed digits in the date of birth or the donor number can delay the search. Though the system automatically intercepts many errors, we check the processes and help ensure that the records are correct and that the data forwarded is accurate. We can therefore avoid sharing incorrect information. These careful checks necessitate utmost attention and precision, every day.

Question: What challenges and tasks does the search team face in addition to the donor search?

Answer: Besides searching for donors, the team also handles CT discrepancies, contact between patients and donors, and follow-ups. One particular challenge is to support transplant centers with related donations when a family member lives abroad. In such cases, the team examines the possibilities in the country where the relative lives and which institution they should contact first. The transplant center can then proceed with the subsequent steps itself.

Question: What motivates you personally in your work as part of the search team?

Answer: We are motivated by the varied work and the contact with people from all over the world. Sometimes the search can be intensive and demand creative solutions. It is particularly satisfying to see a suitable donor being found – especially when children are involved. It feels good to know we are helping save lives. This responsibility motivates us to go one step further: This could mean quickly forwarding a request, even after hours, or managing an urgent query just before the weekend. It's simply a great feeling to be there for patients and not to waste any time.

“It's simply a great feeling to be there for patients and not to waste any time..”

4,448 searches
for German
patients

Digital, binding, process-oriented – The new digital workup

The introduction of the digital workup process in BMDnet marked a further milestone in the digital advancement of transplant coordination. Transplant centers in Germany can now file their workup requests – directly in the system – in fully digital format without paper forms, media discontinuity or time-consuming post-processing.

The workup process, which was previously manual and therefore prone to error, is now a structured, digitally supported process that ensures clarity, speed and security. This benefits everyone involved.

Standardized and flexible at the same time

The requirements are recorded directly in the protected area of BMDnet, where two different user roles are set up for the coordinators and physicians at the transplant centers: one for administrators and one for approvers. Workup requests can be created and processed by administrative users, whereas approval can only be given by authorized users. This ensures that the approval for any request is legally sound and fully traceable – no additional signatures or external communication is necessary.

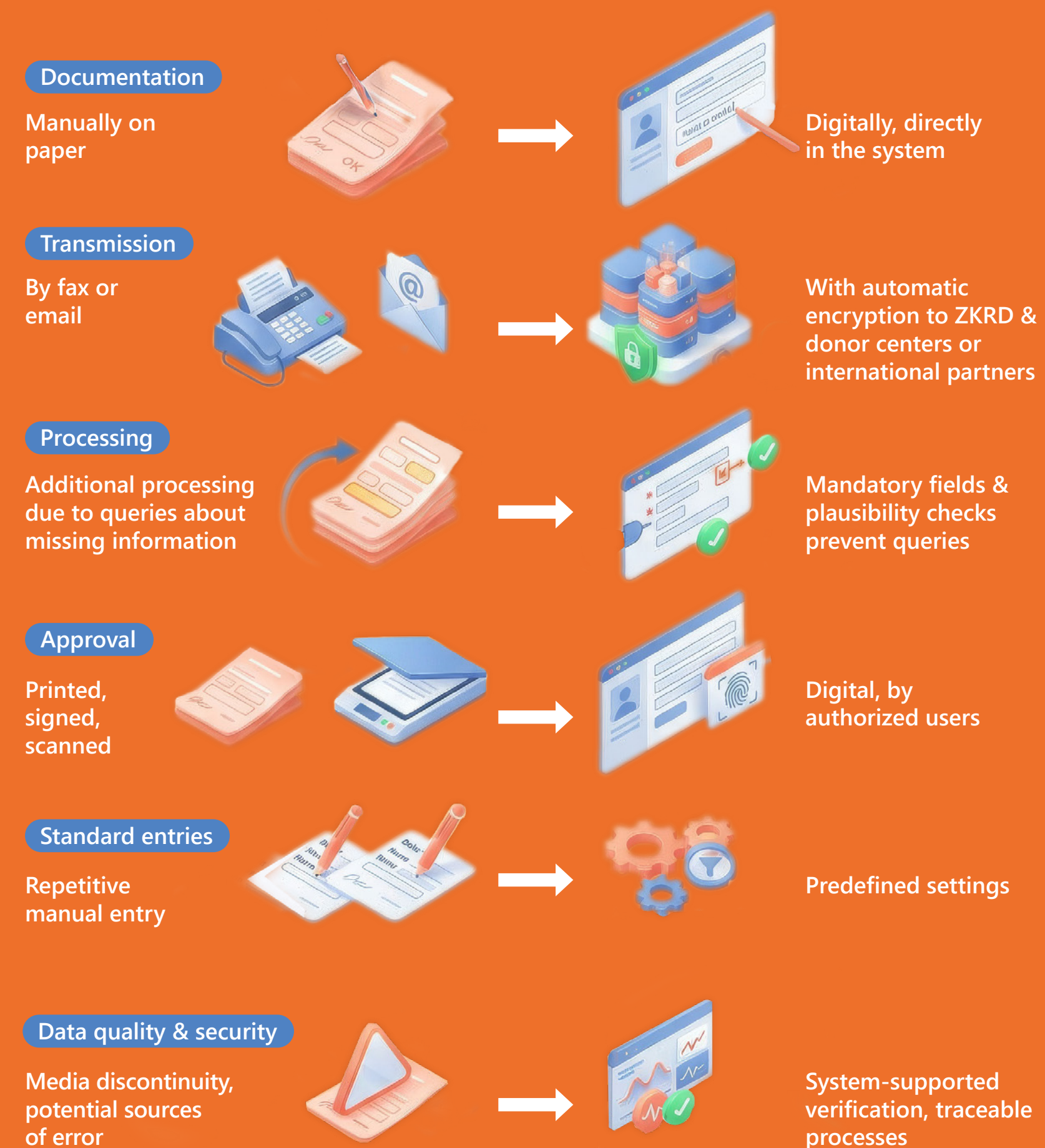
To simplify recurring entries, pre-settings can be used. These are pre-defined settings for frequently used information, such as transport conditions, addresses and sample requests. This information is pre-populated when creating a new request but can be modified manually as necessary. This noticeably relieves the burden on transplant centers in their daily routine.

Focus on process reliability and data quality

In addition to saving time, digital workups also offer qualitative benefits. Mandatory fields and integrated plausibility checks ensure that all the required information is transmitted completely and correctly. Follow-up queries due to missing details are therefore a thing of the past. Approval is granted without any media discontinuity and in encrypted form – an important contribution to data security and traceability.



Then and now: How the workup process has evolved



Manufacturing authorization for collection centers abroad

Manufacturing authorization for collection centers abroad

Government offices and state authorities are increasingly sending targeted inquiries to transplant centers to determine whether the required evidence of a manufacturing authorization is available for collection centers abroad. This has resulted from the heightened regulatory requirements placed on the import of hematopoietic stem cells and an increase in official checks on compliance with European quality and safety standards.

German law expects the manufacturing process, including infectious-disease marker testing, to be GMP-compliant prior to the import of hematopoietic stem cells. This is ensured by requesting a manufacturing authorization from the collection center and by obtaining evidence of the laboratory's certification or a "supplier qualification statement." Responsibility for providing such proof lies with the importer – usually the transplant center. The manufacturing authorization serves as formal proof that the quality and safety of the product comply with the relevant European standards.

Challenges in practical implementation

Various challenges can arise when implementing the regulatory requirements in daily practice:

- **Document procurement:** Manufacturing authorizations and laboratory accreditations cannot always be obtained in full or at short notice.
- **Different standards:** National legal requirements and test procedures sometimes vary considerably.
- **Language barriers:** Documents are often only available in the local language and are difficult to assess.
- **Inconsistent equivalence assessment:** The conditions under which the standards of other countries can be deemed equivalent to EU requirements are not always clearly defined.

Legal framework

The collection and import of bone marrow or peripheral blood stem cells are subject to clearly defined legal requirements:

- **Approval requirements as per sections 72 and 72b German Drug Law (AMG)** for bone marrow and peripheral blood.
- **EU Directive 2015/566** with requirements for the collection, processing, storage, use and equivalence testing of third-country standards.
- **AMWHV and EU-GMP guidelines** for manufacture, testing, documentation and release under quality-assured conditions.
- **Aide-Mémoire 07120506** (monitoring of blood donation facilities) of the ZLG* as official inspection guidance on the requirements for personnel, premises, quality management, documentation and transport.

These regulations and administrative aids serve to protect patients and aim to ensure that imported products meet European quality and safety requirements.



* Central Authority of the „Länder“ for Health Protection with regard to Medicinal Products and Medical Devices.

5 Manufacturing authorization for collection centers abroad

Possibilities in the event of an inadequate manufacturing authorization

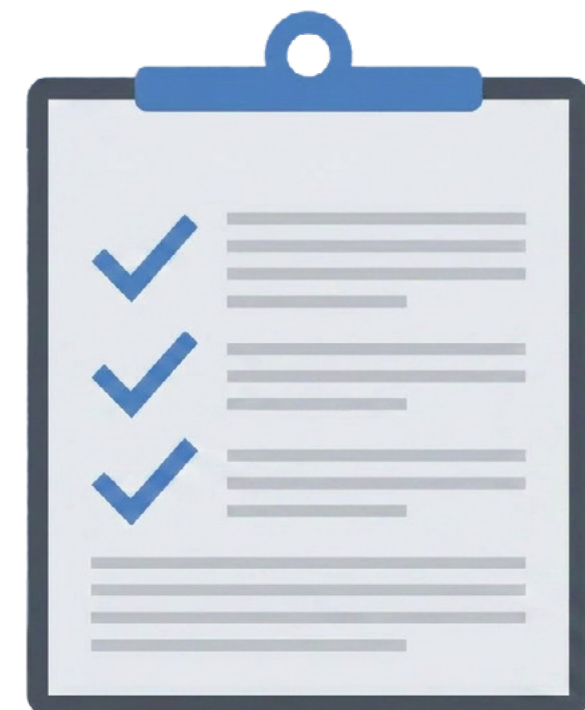
If the submitted manufacturing authorization or the information it contains is insufficient, this can be resolved in various ways:

- Closer individual examination of the available quality and safety evidence
- Additional medical and laboratory checks prior to transplantation
- Foregoing import in favor of alternative donor or product options, if applicable

Examples of possible medical and laboratory checks

In principle, it is possible to thoroughly check the medical information and donor samples prior to transplantation, for instance by:

- requesting pre-collection samples to retest the relevant parameters at the laboratory with which the transplant hospital works
- reviewing the information in the donor-clearance document
- reassessing the medical information to determine the reliability and quality of the analyses at the collection center



Additional checks may also be carried out upon receipt of a stem cell preparation – for example:

- Checklist-based verification of regulatory requirements (identity, labeling, transport conditions)
- Laboratory checks such as viability, CD34⁺ cell count and, if necessary, immune-cell subpopulations
- Comparison against previous results

Support from the ZKRD

International manufacturing and testing standards can vary significantly. The ZKRD provides transplant centers with organizational support in this process and ensures they have all the relevant documents. This service is already included if transport is organized by the ZKRD, but it can also be requested separately.

Nevertheless, the obligation of proof remains with the importer, meaning the transplant centers assume central responsibility for the regulatory and medical assessment of imported products.



Conclusion

The manufacturing authorization of the collection center is an important formal component of quality assurance, but on its own does not provide a full guarantee of product safety. Delivery of a safe transplant of high quality, despite the varied international standards, is only possible through the interplay of regulatory requirements, medical and laboratory testing at the transplant centers, and supporting organizational processes.

Thank you

We wish to thank Dr. Daniela Wehler for her talk, "Manufacturing authorizations of collection centers in third countries: Purpose and challenges from the perspective of UM Mainz." Her explanations provided valuable insights and formed the basis for this article.

Everything at a glance: The new ZKRD partner section

After more than a decade, the ZKRD partner section has been completely redesigned. The structure that had evolved over the years no longer met today's requirements for user navigation, clarity and layout. Some content had become difficult to locate, navigation was inconsistent, and the overall appearance was outdated. The redesign was closely coordinated between all ZKRD departments while considering a wide range of feedback from our partner network. In addition to visual and structural improvements, the content of the section was updated and expanded.

From concept to implementation

Internal analyses, technical requirements, and specific feedback from our partners formed the starting point of the project. The existing structure was jointly evaluated, revised and redesigned. An online survey was also conducted, the results of which were fed directly into the redesign. Aspects such as IT security and data protection were also fully considered throughout. The new partner section meets current technical and legal requirements and ensures that protection and functionality are equally guaranteed.

The question of how to make access to relevant information simpler, more intuitive and more efficient was at the heart of the redesign. The result is a clearly structured platform with a modern design and purpose-built information architecture. Orientation is easier thanks to a simplified layout, clearly organized areas and intuitive menu. The thematic structure has been revised; the content has been tagged with precise keywords and organized logically into subcategories. The new homepage serves as the central entry point, offering access at a glance to recent newsletters, announcements in the "News section", and quick links to key areas such as S(P)EAR, contact information and the feedback form.

Updated, expanded and user-friendly

The entire content was carefully revised as part of the relaunch. Outdated information was removed, incorrect links were fixed, and new material was added – especially in the forms, statistics, contracts and regulations sections. The information provided has also been expanded: Under "ZKRD and our Services," information is available about services and support options, organized by topic. A dedicated download area provides direct access not only to the forms, but also to figures and analyses from the annual report – something our partners have often requested.

Suggestions and comments can be submitted at any time under "Ideas for improvement." This feedback is evaluated systematically and contributes to ongoing development.

The success of this project was only possible thanks to the involvement of many contributors who shared their expertise, critically examined processes, and restructured the content. Well-founded suggestions from external partners also made a valuable contribution to further development. This close, constructive collaboration was a key success factor – our sincere thanks go to everyone involved.

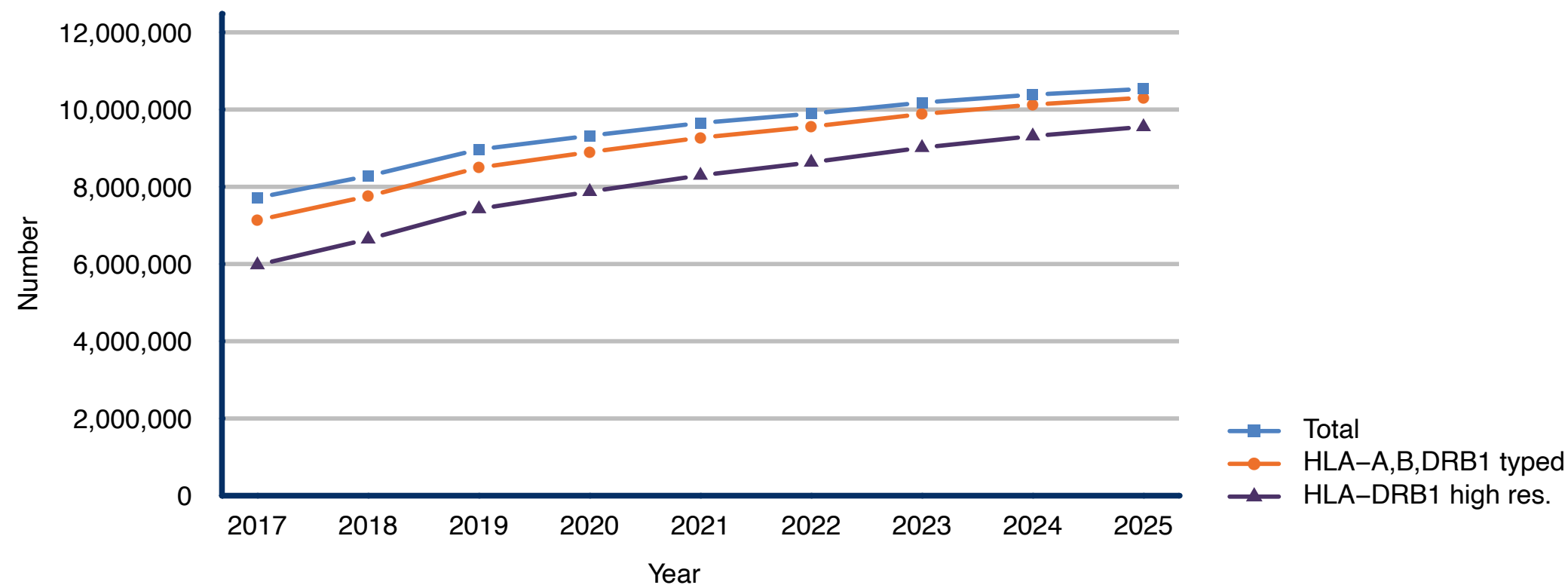


2025

As in previous years, we would once again like to draw your attention to our statistics – they provide reliable facts while offering scope for well-grounded interpretation. They give insights into key trends, the progress that has been made, and the areas where further action is still required. In doing so, they form a reliable basis for assessing the current situation and better understanding future developments.

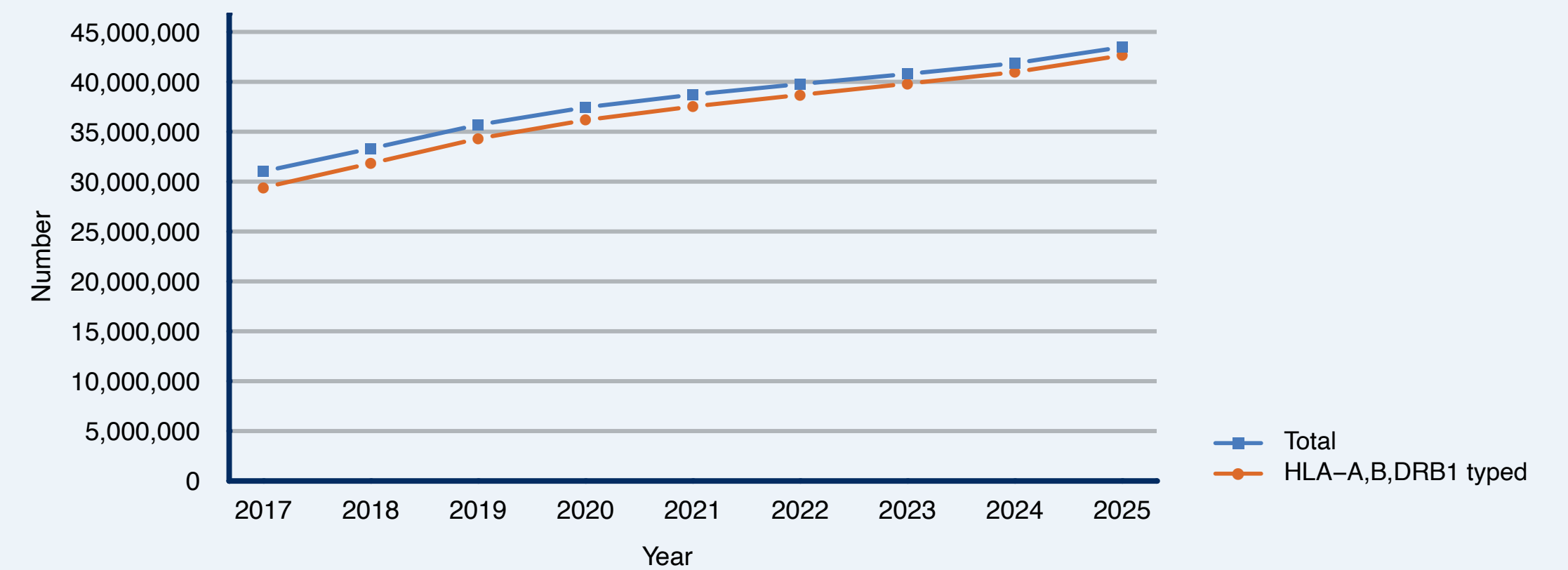
In 2025, the total number of registered donors in Germany rose to almost **10.6 million**. This increase amounted to just under **150,000 donors** – by far the lowest figure in the past 20 years, but still significant given the overall total and therefore a testament to the **success of the combined effort to recruit new donors**.

German donor numbers

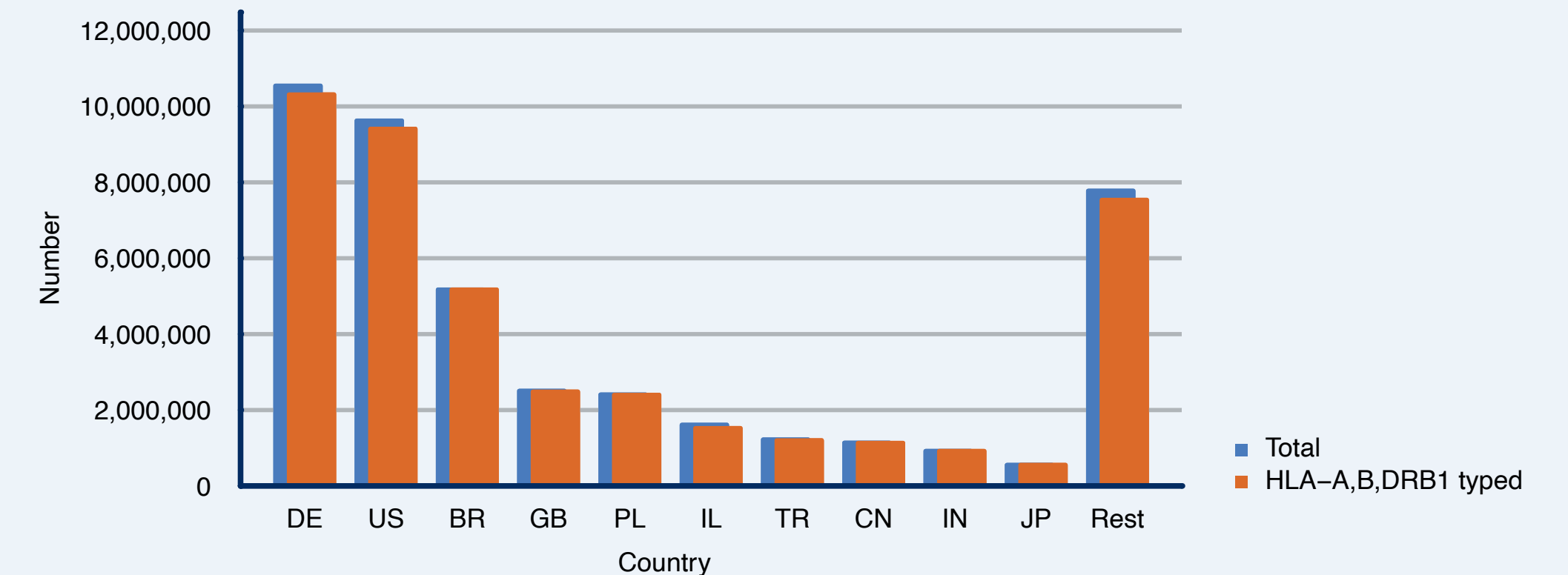


With a **total increase in the donor pool of 1,617,095**, Germany recorded the highest growth worldwide in 2025. India ranked second with just under 134,000 newly recruited donors, followed by Great Britain with slightly more than 80,000. In the United States, by contrast, the donor pool decreased in 2025 by around one thousand donors – a development likely attributable, at least in part, to changing societal conditions. **With almost one million donors more than the United States, the ZKRD continues to maintain the world's largest national registry, accounting for roughly 25 % of all donors worldwide.**

Global donor numbers (according to the WMDA)



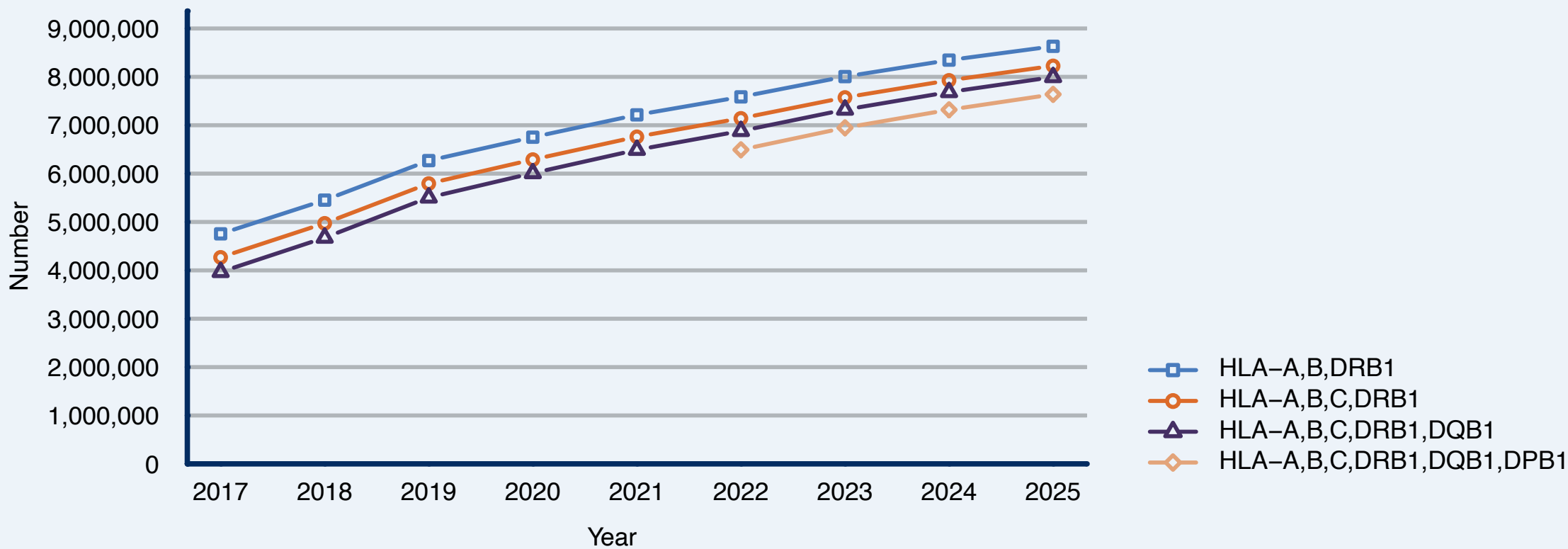
Distribution of donors worldwide (according to WMDA) in 2025



7 Statistics

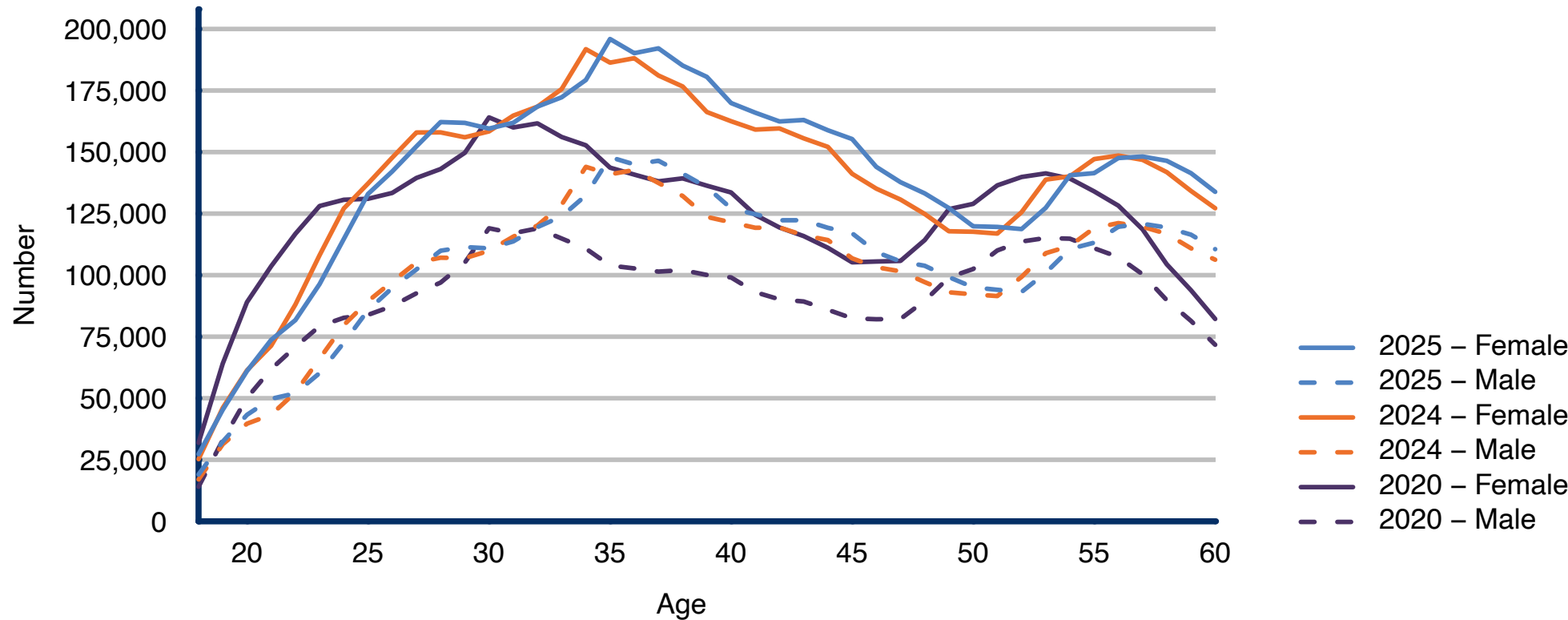
The proportion of donors high-resolution typed at the **five gene loci (HLA-A, -B, -C, -DRB1 and -DQB1)** increased slightly again in 2025. Consequently, almost **76% of donors** can now be assigned directly without the need for probability calculations or confirmatory typing. This development has resulted in particular from the growing use of **modern methods such as next-generation sequencing (NGS)**, which offer a cost-effective way to achieve full high-resolution typing upon initial donor registration or during prospective retesting of donors who are already registered and were previously typed at low resolution. In addition, the removal of legacy low-resolution datasets from the database has contributed to this relative increase.

Donors in Germany typed at high-resolution

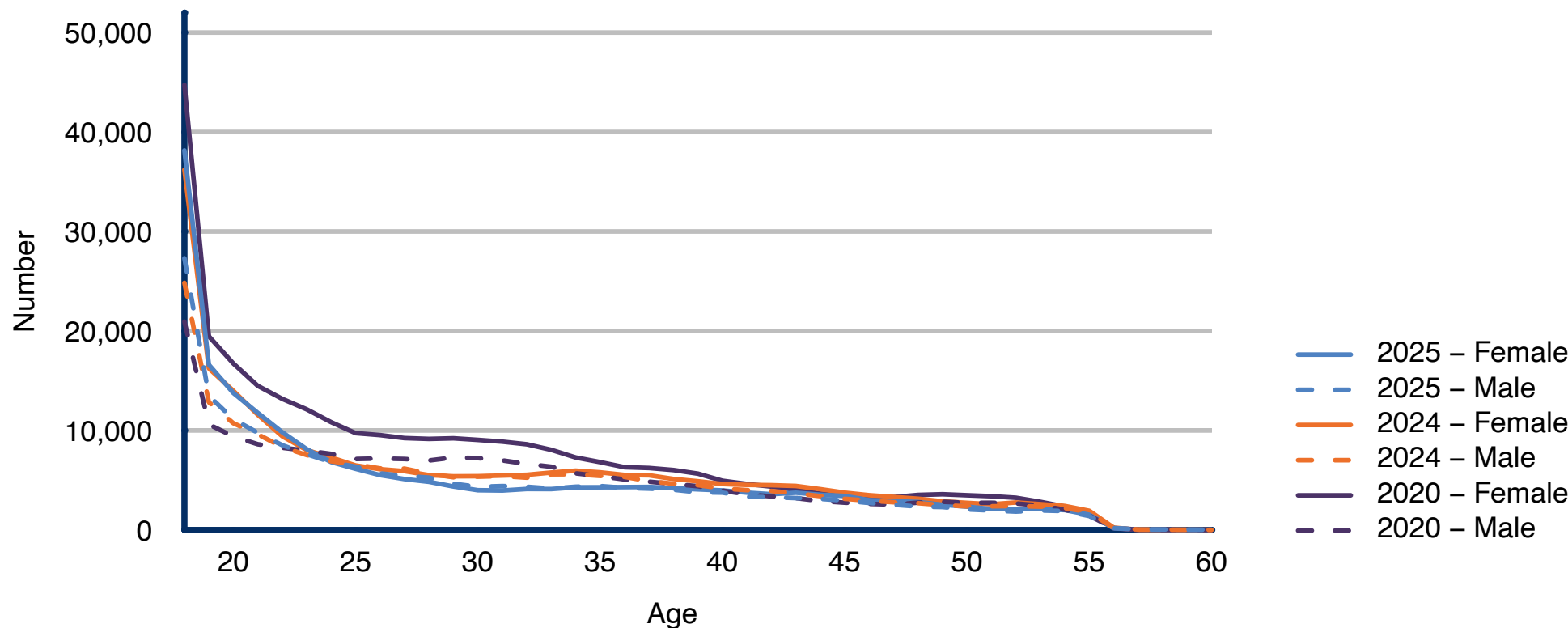


The age distribution of donors registered in Germany showed two peaks in 2025. **The peak at age 57 is steadily approaching the upper age limit of 60, after which donors are retired from the registry; hence, a growing number of donors will no longer be available in the near term.** This foreseeable loss clearly illustrates how important it is to motivate people to register. It is particularly relevant that, in addition to HLA matching, stem cells from young donors have a decisive impact on transplant outcomes and are therefore preferred. To ensure the best possible patient coverage, recruitment of young people into the registry remains indispensable and must be continuously strengthened.

Age distribution of German donors



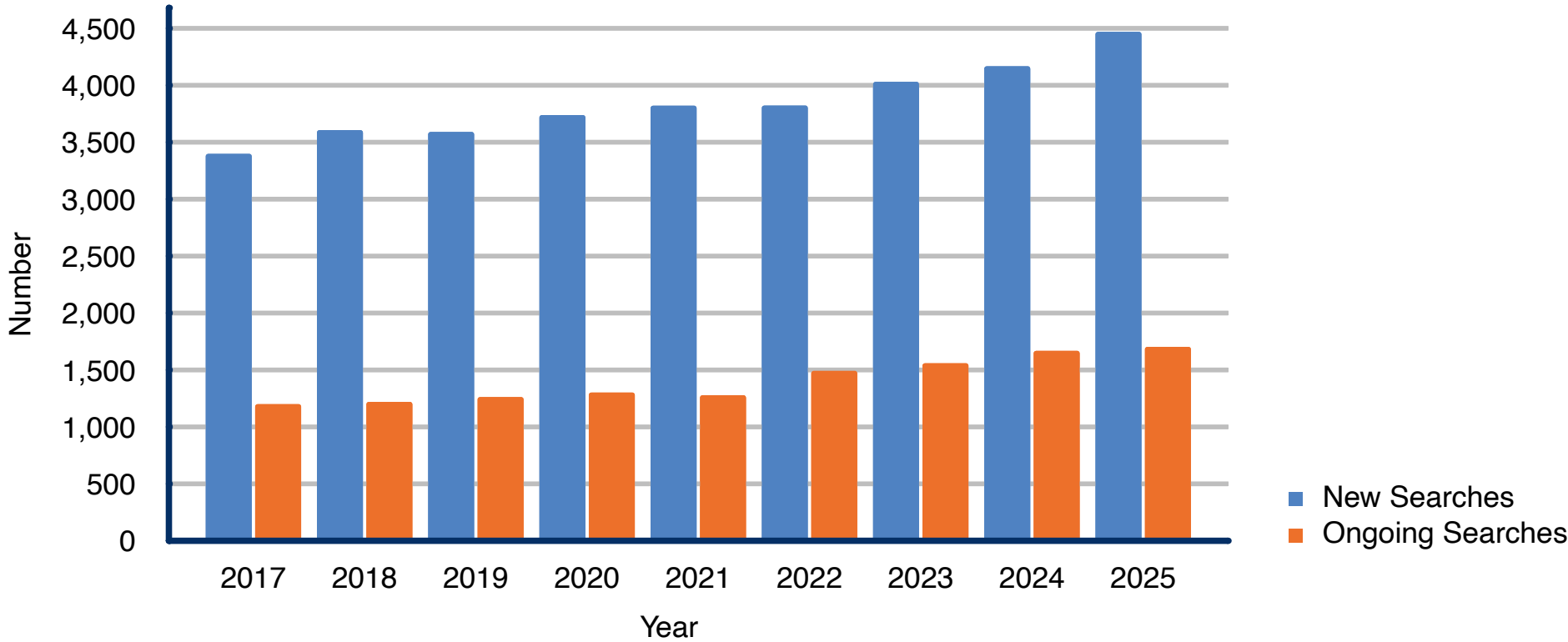
Age distribution of newly recruited donors



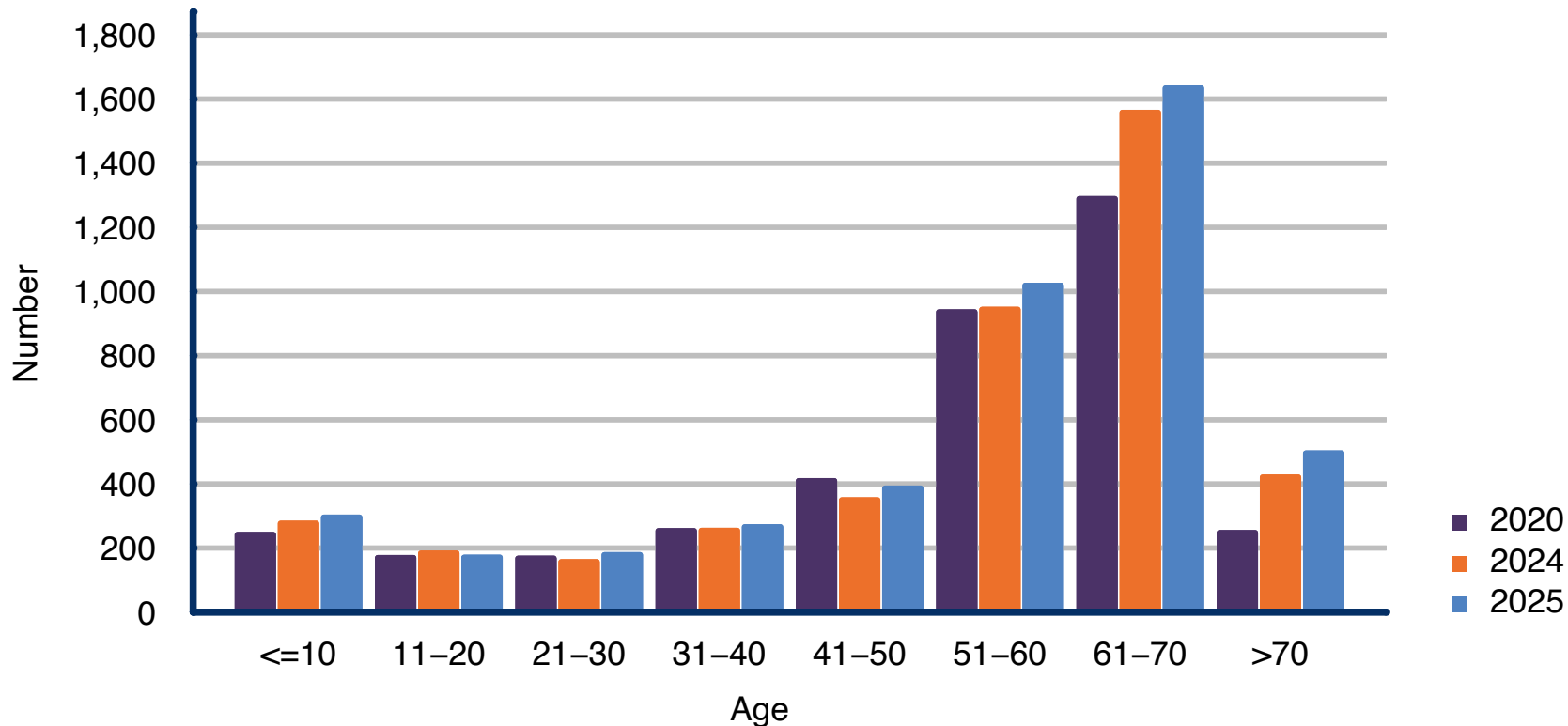
7 Statistics

In 2025, the total number of new searches initiated for German patients reached an exceptionally high level at 4,448, continuing the trend observed since 2017 and representing an increase of 7.28% compared with the previous year. In parallel, the age distribution of German patients has shifted noticeably, with a marked **rise in the age groups above 51 years** – a development that highlights the quality and success of blood stem cell transplantation along with all the advances achieved in recent years.

Donor searches for German patients

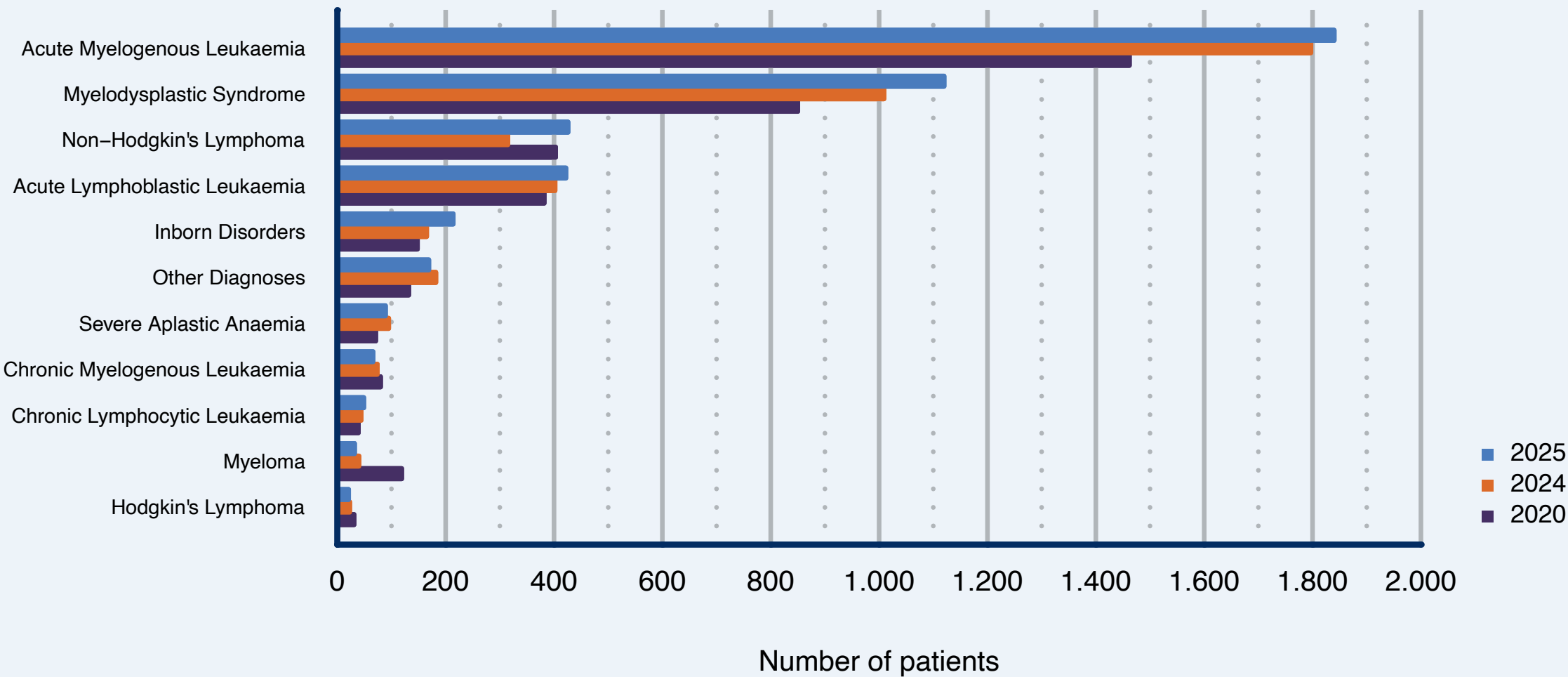


Distribution of German patients by age



The partially age-associated diseases AML and MDS once again appeared more frequently as the indication for a blood stem cell transplant compared with the previous year. The number of cases involving multiple myeloma has continued to decline sharply, while CML, CLL and non-Hodgkin lymphomas have remained at a stable level for many years.

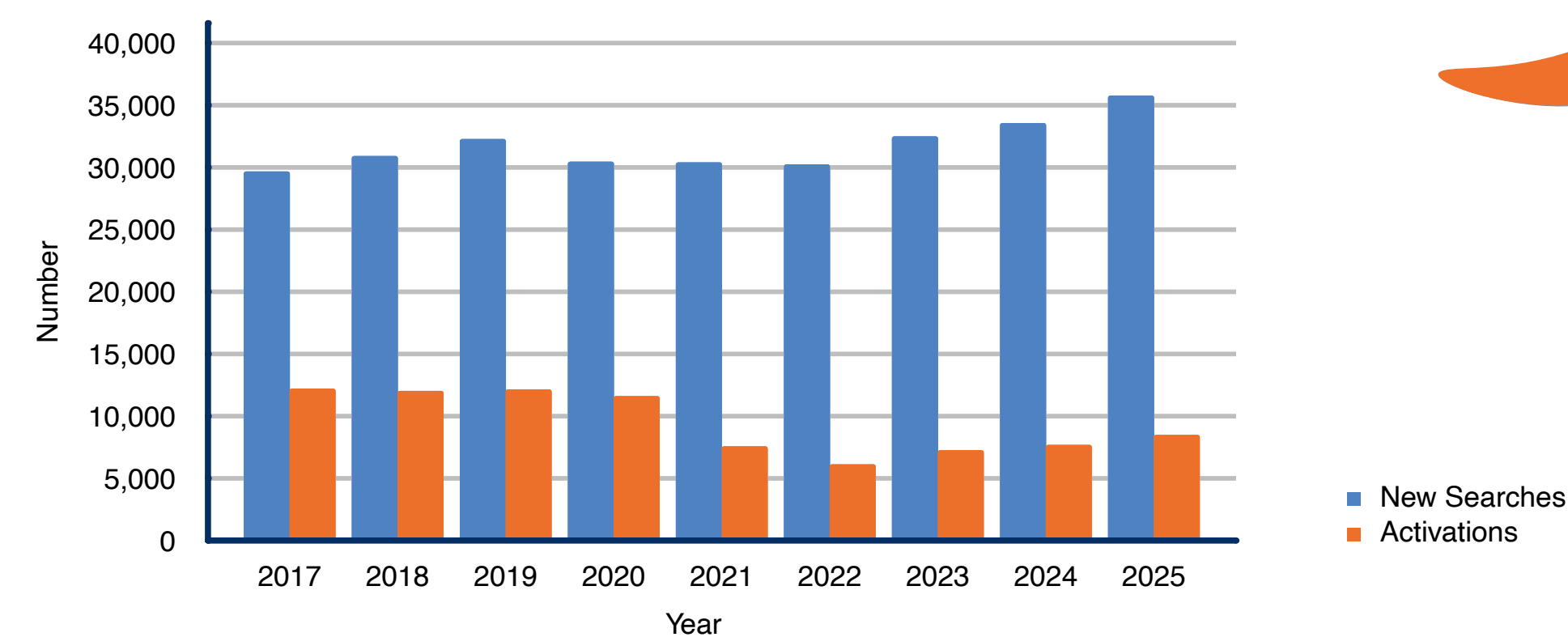
Distribution of diagnoses of German patients



7 Statistics

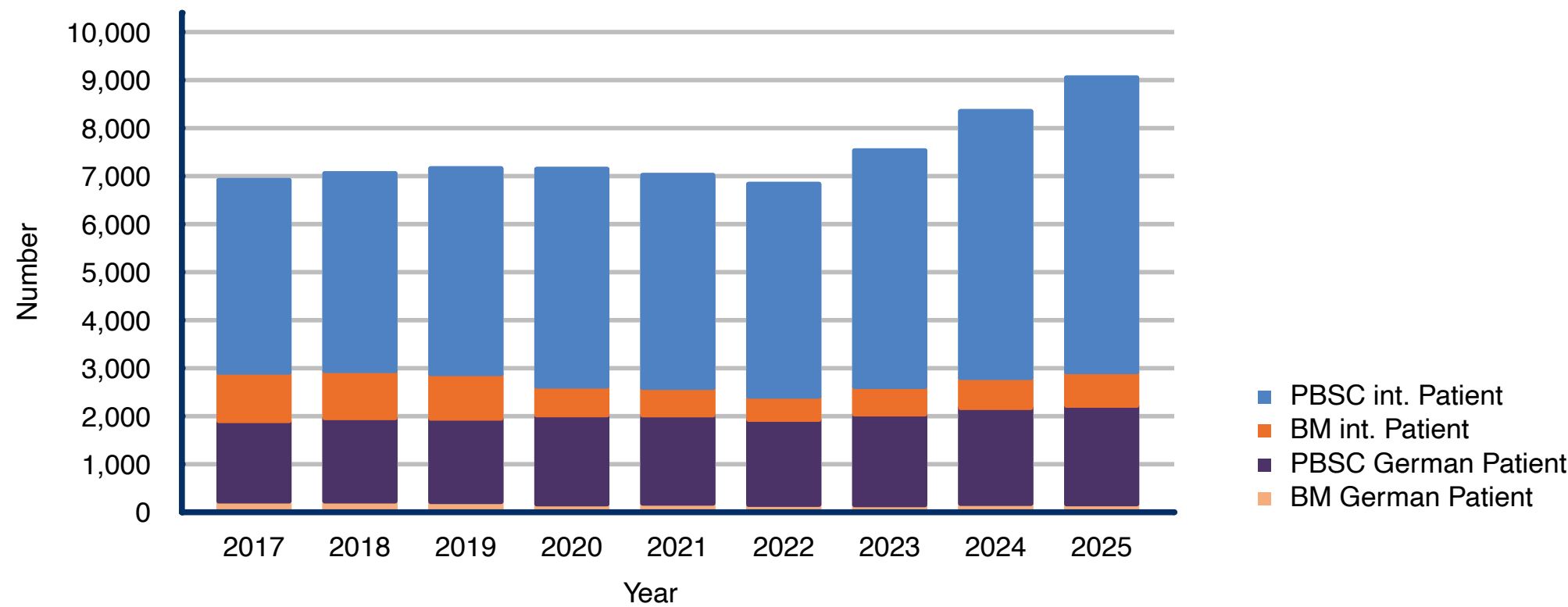
Progress in transplant immunology and oncology is also advancing rapidly abroad, as reflected in the number of search requests from other countries in 2025, rising by almost **7% to a record high of nearly 35,600**. At 59%, the USA was once again the largest requester, significantly ahead of the European countries, with France leading at 6.5%. One reason for this is certainly the historically strong pattern of emigration from Germany to the United States: it is not unusual, due to shared ancestry, for American patients to find their genetic match in Germany.

Donor searches for international patients

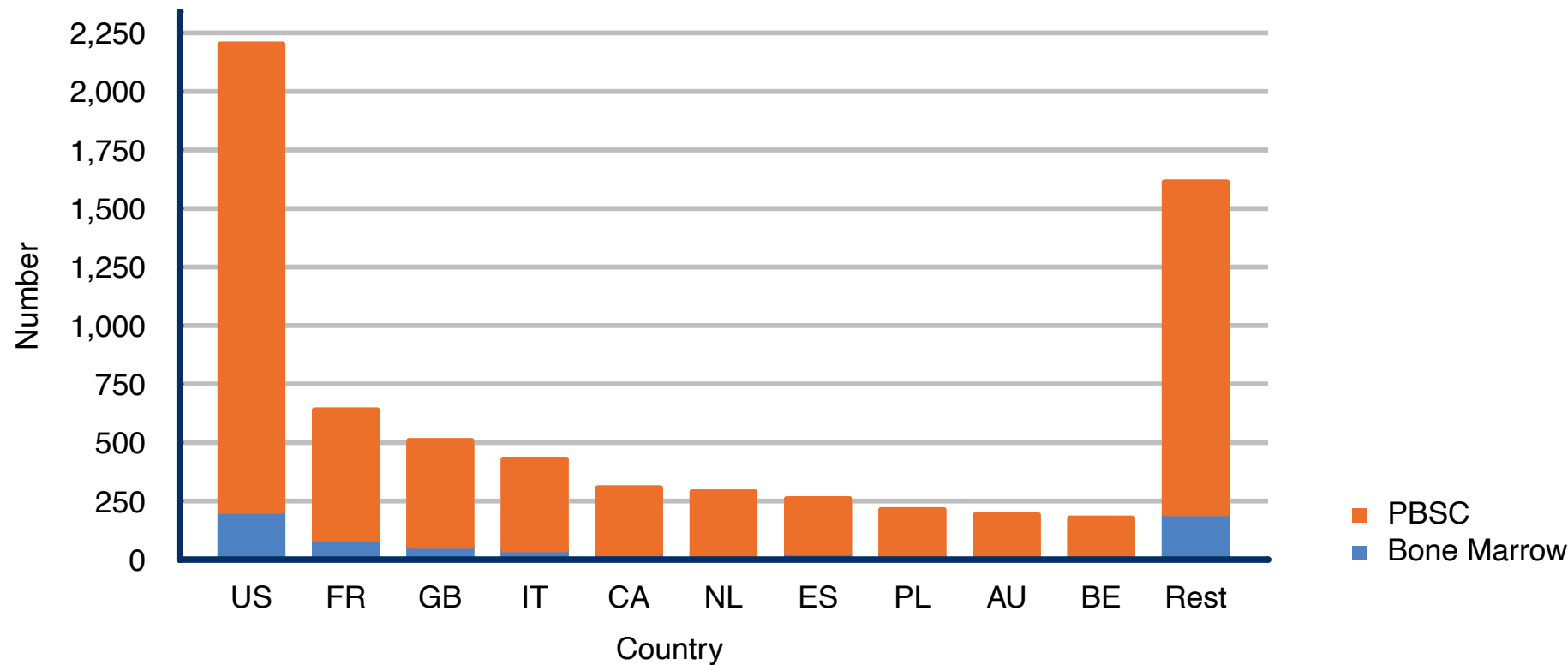


In 2025, a record number of 9,049 collections from German donors was reached, having **increased by 8.4% and therefore exceeding the threshold of 9,000** for the first time. Notably, the increase was smaller among domestic patients at **2.3% compared with a significantly larger rise of 10.5% for international patients**. This again reflects the transplant successes abroad and emphasizes the importance of German donors to patients both nationally and international-ly. Special thanks therefore go to all registered donors in Germany, as well as to all the partners involved who, through their collective efforts, do an exceptional job day after day, working effi- ciently and to a high standard under all conceivable conditions to ensure that patients receive the care they need.

Blood stem cell donations from all German donors



Distribution of donations from all German donors for international patients in 2025





ZKRD

**Zentrales Knochenmarkspender-Register für die
Bundesrepublik Deutschland gemeinnützige GmbH**

Postbox 4244, 89032 Ulm
Helmholtzstr. 10, 89081 Ulm
Fon 0731 399 679-000
info@zkrd.de
www.zkrd.de