



ZKRD Zentrales
Knochenmarkspender-
Register Deutschland

ANNUAL REPORT 2022/2023

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1 Preface

Finding the best transplant for every patient with competence and neutrality on a global scale is our primary goal

– one that we, as a central coordination center, actively pursue. This also includes efficiently shaping the processes from donor search through shipment of the transplant to the patient. The importance of such a central coordination center becomes especially apparent under difficult circumstances, such as during the coronavirus pandemic. But the ZKRD is also on hand when unexpected problems arise within routine procedures. In the past year, we were once again able to support our partners in numerous ways, such as in sourcing bone marrow collection kits in the European Union when the familiar means of delivery were jeopardized by the demanding requirements of the Medical Device Regulation (MDR). In this regard, the ZKRD and its partners at national and European levels worked closely together to find a feasible solution.

We have also made great progress with digitalization: By implementing additional features in the ZKRD's own BMDnet software system to facilitate a quick overview and direct access in the workup area, not only has efficiency been increased, but further error minimization is ensured. Aside from these new capabilities, cooperation and transparency between the stakeholders can also be strengthened in this way.

We have also achieved a great deal together – along with those working at the transplant centers, search units, donor centers and receiving units, we strive each day to find the most suitable donor for every patient as quickly as possible. Steve Jobs once said: "The only way to do great work is to love what you do." This speaks to us from the heart. Thanks to the passionate commitment and many years of collaboration of all those involved, we achieved two milestones last year: In the spring, Germany registered its 10 millionth donor, while over the year a record number of stem cell collections took place.

We would not have achieved this without our partners and therefore thank them for supporting us with their expertise, time, and resources. Together, we intend to continue pursuing our life-saving mission: "Faster identification of the best donor worldwide for every patient!"

However, our biggest thanks go to the many millions of volunteers who have registered as potential donors or have already donated. Their extraordinary commitment gives many critically ill people a glimmer of hope.

Dr. Peter Mein

PD Dr. Joannis Mytilineos

Volker Rump

“

I understand the impact a cancer diagnosis has. I am aware of the fears that patients and their families face and how eagerly they wait for "the call" and a life-saving donation. And from my own experience I know that saving a life leaves you with a lasting sense of happiness.

Bodo Ramelow, Minister-President of Thuringia



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PD Dr. Joannis Mytilineos

Foreword

The ZKRD reached a significant milestone in April 2023

when the 10 millionth donor was registered in Germany. This impressive figure represents not only the strong sense of community in our society, but also the immense hope it gives to people who have a life-threatening condition. Despite global challenges, many volunteers have supported our goal. Last year, 503,548 potential donors signed up for the first time – a decision that demonstrates both courage and selflessness. The motives behind such a decision are diverse: from personal experiences to empathy. All those who are willing to donate have their own unique story but share the desire to save lives. Given the large number of donors registered in Germany, it is hardly surprising that a second record was set in 2023: With around 7,500 collections, more people donated their stem cells within one year than ever before in the ZKRD's 30-year history. These donors are true heroes whose support is greatly appreciated.

The social commitment of donors and those willing to donate does not go unnoticed:

Ten million – what a fantastic achievement. This not only demonstrates the willingness of people to donate, but also the effectiveness with which information on the topic is being spread.

Ursula Nonnemacher, Minister for Social Affairs, Health, Integration and Consumer Protection of the State of Brandenburg

Stem cell donations can be effectively managed thanks to the joint efforts of the ZKRD and the donor centers. With the support of those who are willing to register and donate, these institutions save lives.

Gunter Czisch, former Mayor of Ulm



3 ZKRD annual conference 2023

The ZKRD is the central hub for collaboration between all stakeholders in Germany, from searching for a suitable unrelated donor to transplanting blood stem cells. Representatives from all participating organizations and professional groups in Germany meet every year at the ZKRD annual conference, offering a valuable platform for stakeholder exchange – as was the case on 25 May 2023.

This time, the conference was held virtually to enable the largest possible audience of experts to participate. The focus of the ZKRD annual conference was on operational issues with the aim of optimizing processes and enabling patients to receive even more efficient support in the future. Discussion tables dedicated to the specific topics were set up by the ZKRD to encourage stimulating discourse and effective knowledge sharing among participants.

Particular attention was focused on the issue of cybersecurity. Tobias Scheible, a cybersecurity and IT forensics specialist, explained the dangers of phishing attacks and ransomware and highlighted the increasing threats posed by cybercrime. The ZKRD, for its part, presented information on current risks and reiterated its support with a view to jointly safeguarding the system.

The second main agenda point of the annual conference addressed the support for global partners, especially in difficult situations: Florian Bayer (ZKRD) talked about “Importing blood samples from non-EU countries” and explained the challenges of transporting blood samples between EU and non-EU countries. He demonstrated how global partnerships can be utilized effectively to find solutions to complex cases.

In June 2023, shortly after the ZKRD annual conference, the International Donor Registry Conference (IDRC) was held in Hanau, where the latest scientific findings from the industry in the international context were presented. To avoid overlaps with its own annual conference, the ZKRD made use of these synergies by referring the participants to the IDRC for the usual scientific part of the conference. The intensive exchange meant that we could all make a sustainable contribution to improving blood stem cell searches and transplants. We look forward to the continuation next year, when we will meet again in person in Ulm.



Successful solution for sourcing bone marrow collection kits in the EU

The challenge:

With the introduction of the new Medical Device Regulation (MDR) (Regulation (EU) 2017/745) in the European Union, German transplant centers and receiving units faced a significant problem. The new, demanding requirements of the MDR for the approval of bone marrow collection kits (BMC kits) meant that, given the niche market and the increased effort, manufacturers were no longer willing to apply for CE certification for the European market. It was therefore conceivable that, sooner or later, certified BMC kits would become unavailable and that supplies for patients dependent on the transplantation of blood stem cells from bone marrow would be at risk.

Collaboration at European level:

To obtain a comprehensive overview of the situation, the ZKRD approached various receiving units and European registries as well as the Paul Ehrlich Institute (PEI). It quickly became clear that the threat of supply bottlenecks was greatest in Germany due to the high number of donations, although other European countries were also faced with difficulties. The ZKRD requested the support of the World Marrow Donor Association (WMDA) at EU level. By working closely with the European authorities¹, the representatives of the ZKRD and German professional associations, the WMDA and other European donor registries, the European Society for Blood and Marrow Transplantation (EBMT) and the PEI ultimately found a temporary solution for obtaining BMC kits in Germany.

Working with manufacturers:

When the MDR was introduced, there was only one manufacturer of BMC kits on the European market. The ZKRD assisted the manufacturer in filing an application for special authorization for imports from the USA, although it was initially envisaged that importers (receiving units and transplant centers) themselves should request special authorization directly from the Federal Office for Drugs and Medical Devices (BfArM). Special authorization was granted for one year based on the application. In addition, it was ensured that all institutions making use of the kits could simply reference this authorization.

Extension of the special authorization:

In September 2023, the special authorization was extended for another two years. The ZKRD again contacted the manufacturer and forwarded its documents to the PEI, where they were retained centrally. This permitted a further extension to be effortlessly obtained from the BfArM and a simplified approval procedure at the PEI. The extension of the special authorization also gives the manufacturer time to devise a long-term solution for the supply of certified bone marrow collection kits.

Alternative procedure:

In some European countries, for example in the Netherlands, BMC kits are still assembled from individual components. According to statements and information from a Dutch colleague, institutions such as the Bavarian bone marrow donation

foundation, Stiftung Aktion Knochenmarkspende Bayern (AKB), and the Spanish Registry have developed in-house kits using certified individual components. They are therefore independent and not reliant on foreign suppliers. The validation data from the AKB required for this procedure was shared with all other institutions and was also submitted to the PEI.



Thank you:

We are grateful to all those involved for their cooperation and support, especially our partners at home and abroad, the authorities and the manufacturer. This achievement is a striking example of community spirit and the solidarity shown for our patients. Through these joint efforts, we have managed to guarantee the continued supply of bone marrow products despite the challenges posed by the MDR, even though a more robust multi-vendor solution would be desirable.

1. European Commission, DG HEALTH & FOOD SAFETY (SANTE), Unit B4 – Medical Products: Quality, Safety and Innovation

5 Digitalization in workup

The flow of data between search centers, the ZKRD and international registries is now almost completely automated with the aid of BMDnet, the ZKRD's web-based software solution. However, the challenge of workup, i.e., the coordination of processes from requesting a donation from the appropriate donor to the collection of stem cells, has so far been time-consuming and complex. This could also be improved thanks to advances in the digitalization of processes.



Increasing efficiency and minimizing errors:

Close collaboration with three German transplant centers has paved the way for workup requests to be recorded directly in the system. The required forms are pre-filled automatically with the donor and patient information stored in the search program, leaving only the respective product and patient-specific workup information to be added. This procedure not only significantly reduces the manual effort, thereby saving a lot of time, but also minimizes potential sources of error.

Real-time transparency and improved teamwork

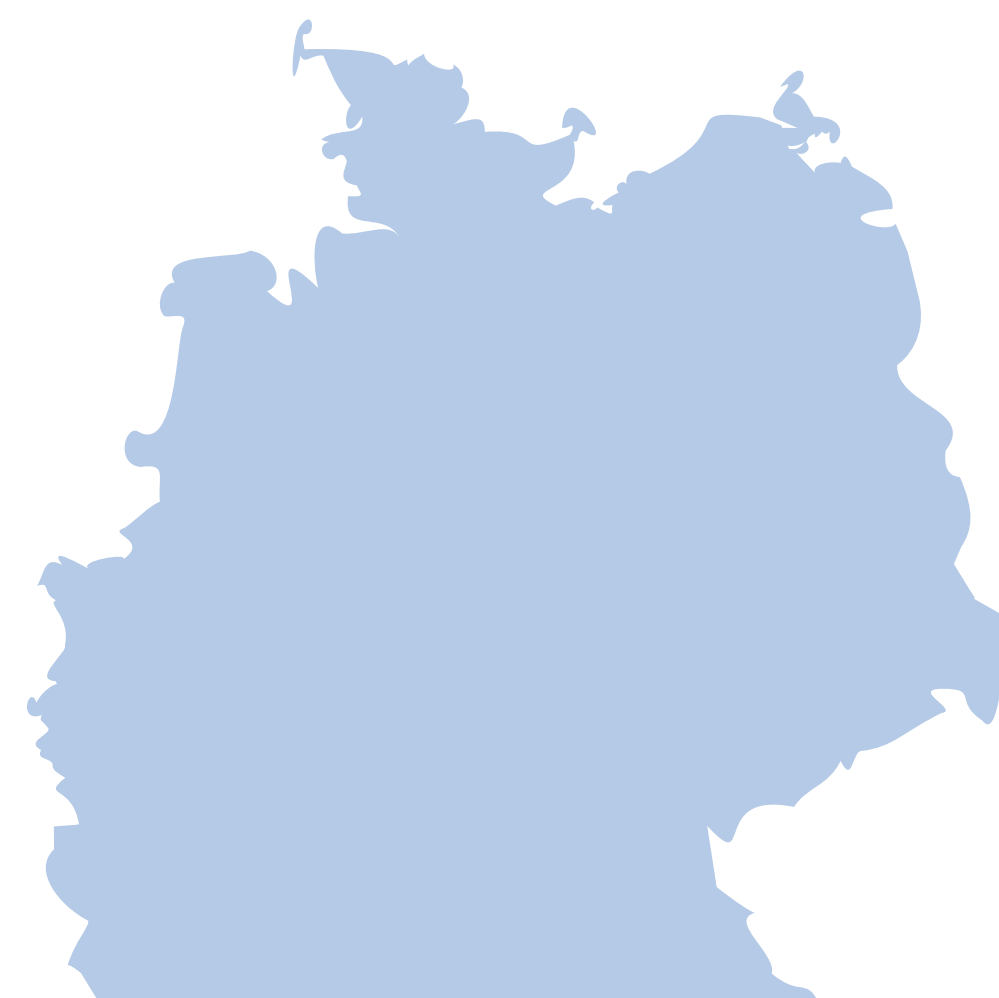
Real-time tracking of status requests offers another significant advantage to the centers that can access the workup program. This increases transparency and enables the teams to immediately recognize and respond to changes. The result is improved communication and collaboration between the respective partners.

Ease of use: Quick overview and direct access

Users also benefit from a quick overview of pending searches for their patients and direct access to patient records. German and international donor lists offer a quick summary of the current donor situation for each patient, supported by a wide range of filter options. The outline of the requests made to date and relevant donor information supports the process of informed decision-making.

Thanks to the teams: Successful test phase and access for all German transplant centers

Our heartfelt thanks go to the three teams at the transplant clinics in Berlin, Freiburg and Ulm who contributed significantly to the successful completion of the test phase, meaning that all German transplant centers can now access the workup program. This teamwork clearly demonstrates how the collaborative efforts of the ZKRD and its partners drive innovation and significantly improve efficiency in the search for unrelated donors.



6 ADCU

The best transplant for every patient worldwide – since 2023, this has included not only the previously familiar sources of stem cells from bone marrow, peripheral blood stem cells and umbilical cord blood, but also adult donor cryopreserved units², or ADCUs for short. Peripheral blood stem cell collection may in some cases yield more blood stem cells than are needed by a patient. If necessary, these cells can be processed and stored for the benefit of another patient and need not be destroyed after a certain period.

Since the DKMS Stem Cell Bank received approval for the production and storage of ADCUs and can thus make them available for worldwide donor searches, the interfaces, and corresponding programs (BMDnet) at the ZKRD have been adapted accordingly in recent months. The ADCUs now appear in the ZKRD donor lists and can be selected by the German search centers when conducting a search.

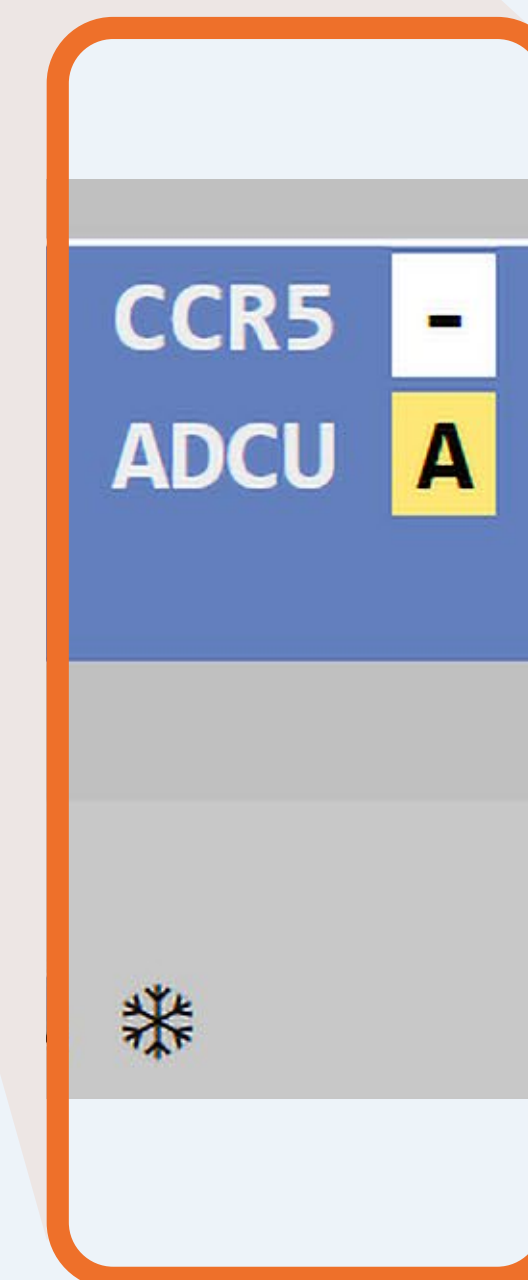
A suitable ADCU can shorten the wait for a life-saving transplant. The use of ADCUs eliminates certain logistical and time-consuming processes, and these excess stem cells mean that a single donor can potentially save more than one life. The inclusion of ADCUs in the ZKRD search system thus contributes in several ways to our enduring goal: “Finding the best transplant for every patient: competently, neutrally, globally.”

Patient	1999	AF	preliminary search				CCR5	HAC	Match	
DE-1 1	F		A	CTs	Ethn	Status		10/10	9/10	8/10
1	Donor		S	M/P	BGr	CMV	ADCU A	TYP	SMP	
	GRID							IDM	WOR	
10/10 (potential) allele matches										
1	DE-ZKRD/DKM	36		AP	AV	G 2023-11	*		AAAAA	
	D000723300063	M							100	0 - 0



The search for suitable donors is a continuous process. Please therefore register and help save the lives of others. Thank you!

Stephan Weil, Minister-President of Lower Saxony



2. Cryopreserved stem cells from adult donors

7 The ZKRD 2023 in figures

2023

Several records were set in 2023

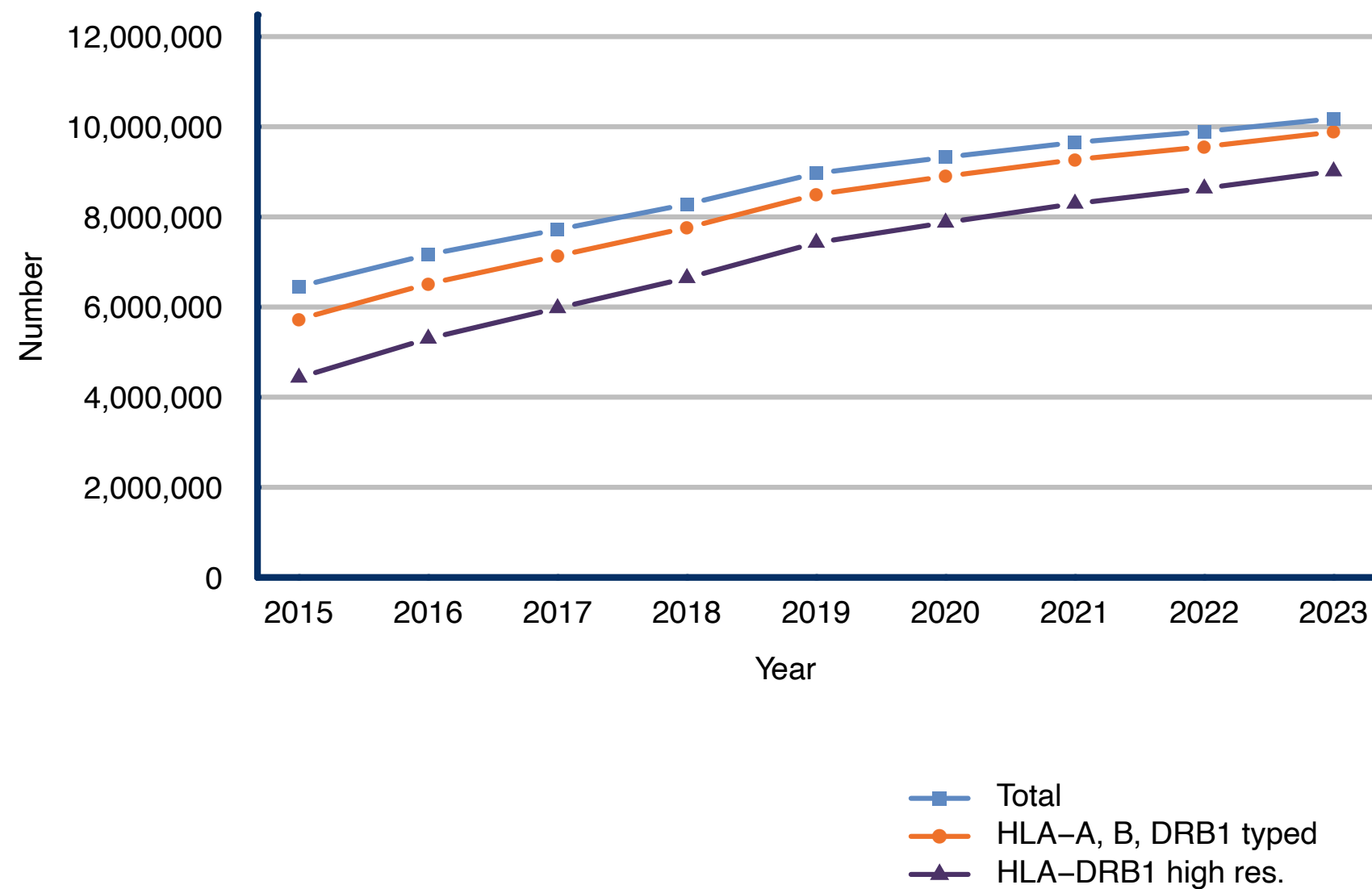


2023:
+ 286.000
donors

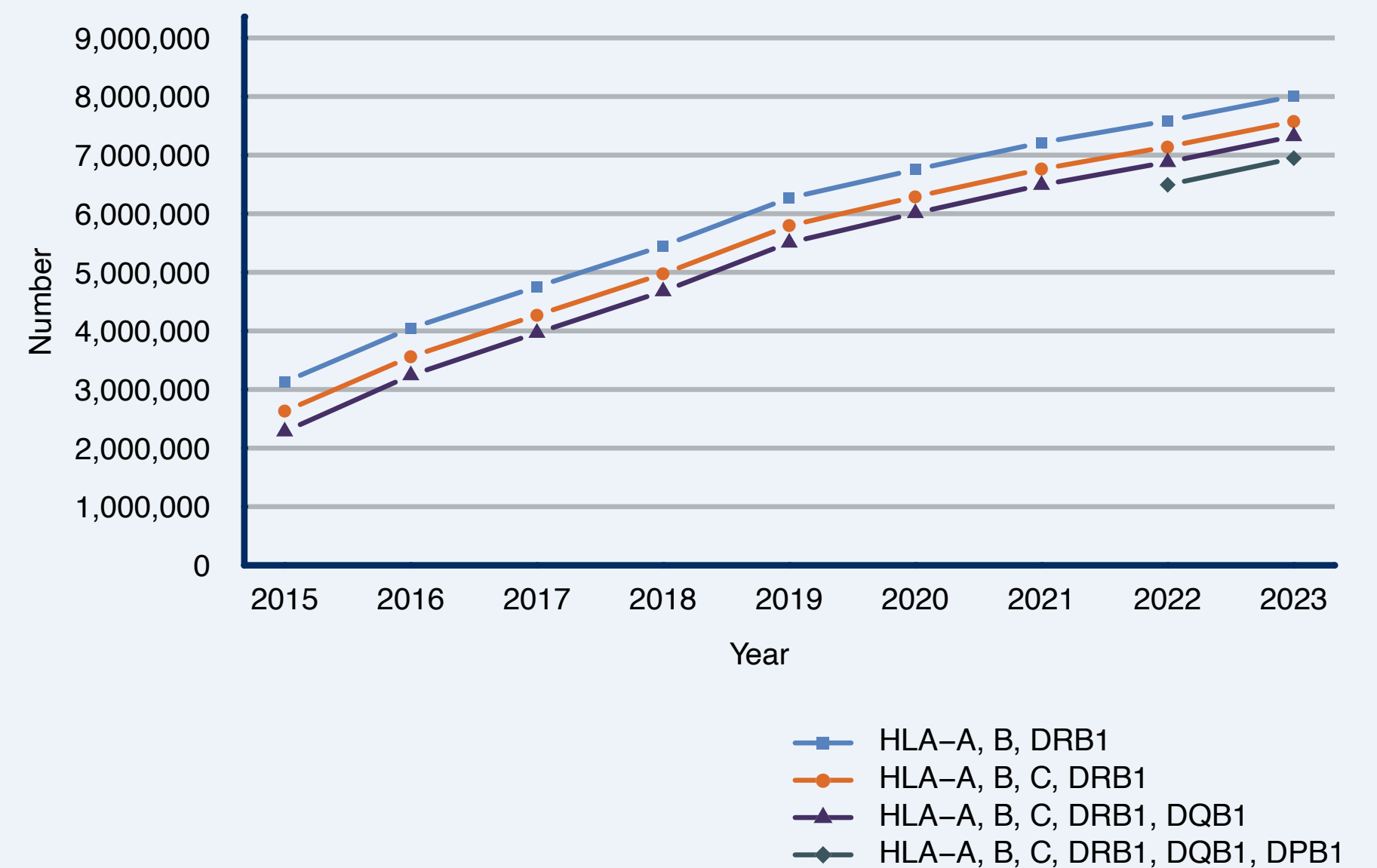
Several records were set in 2023: The total number of German donors peaked at just under **10.2 million**, with the 10 millionth donor already registered by **mid-April**.

Compared to the previous year, the donor pool in Germany increased by a total of **286,000 potential donors**. Due to renewed efforts to retype already registered donors, high-resolution typing for five gene types (HLA-A, B, C, DRB1 and DQB1) was completed in over **70 %** of registered donors in Germany.

1. Donor numbers in Germany



2. Donors in Germany with high-resolution typing



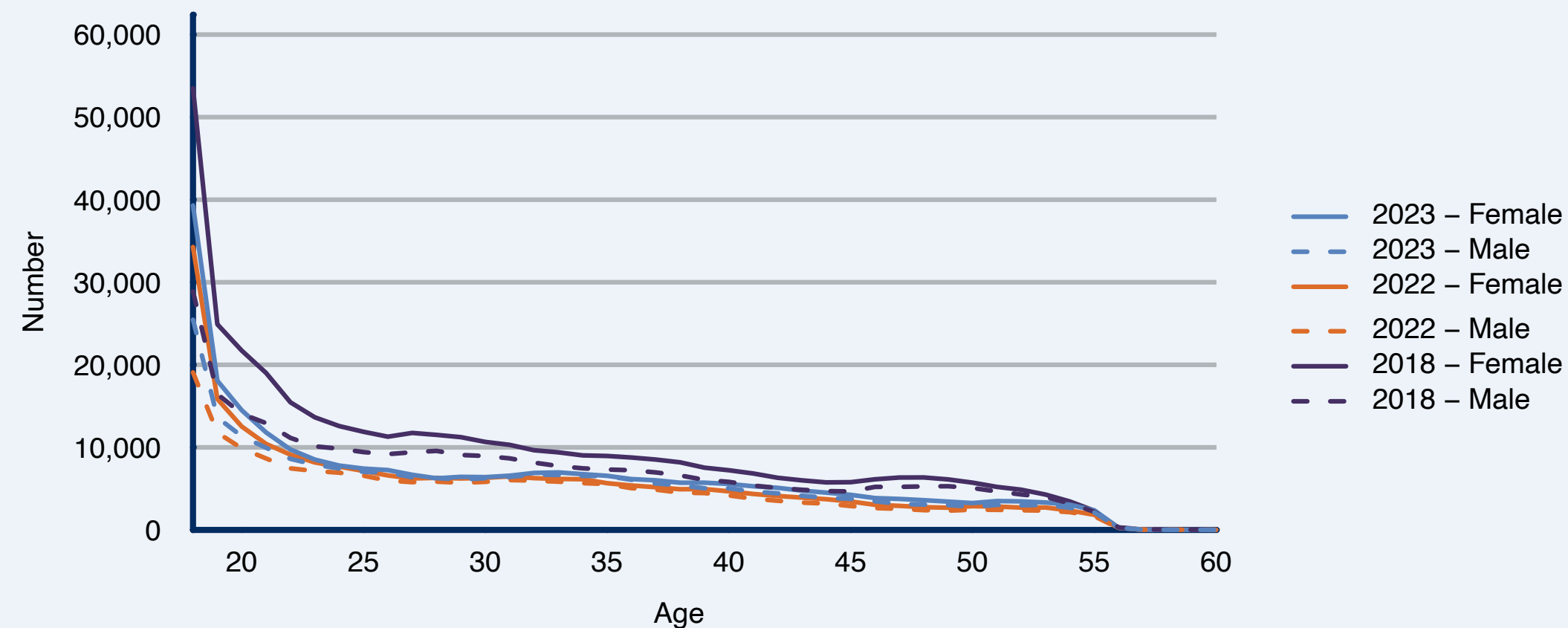
7 The ZKRD 2023 in figures

Despite the tremendous success, encouraging new donors to sign up is crucial, as all those on the right-hand peak of the bimodal age distribution will be removed from the donor pool within the next eight years due to their age.

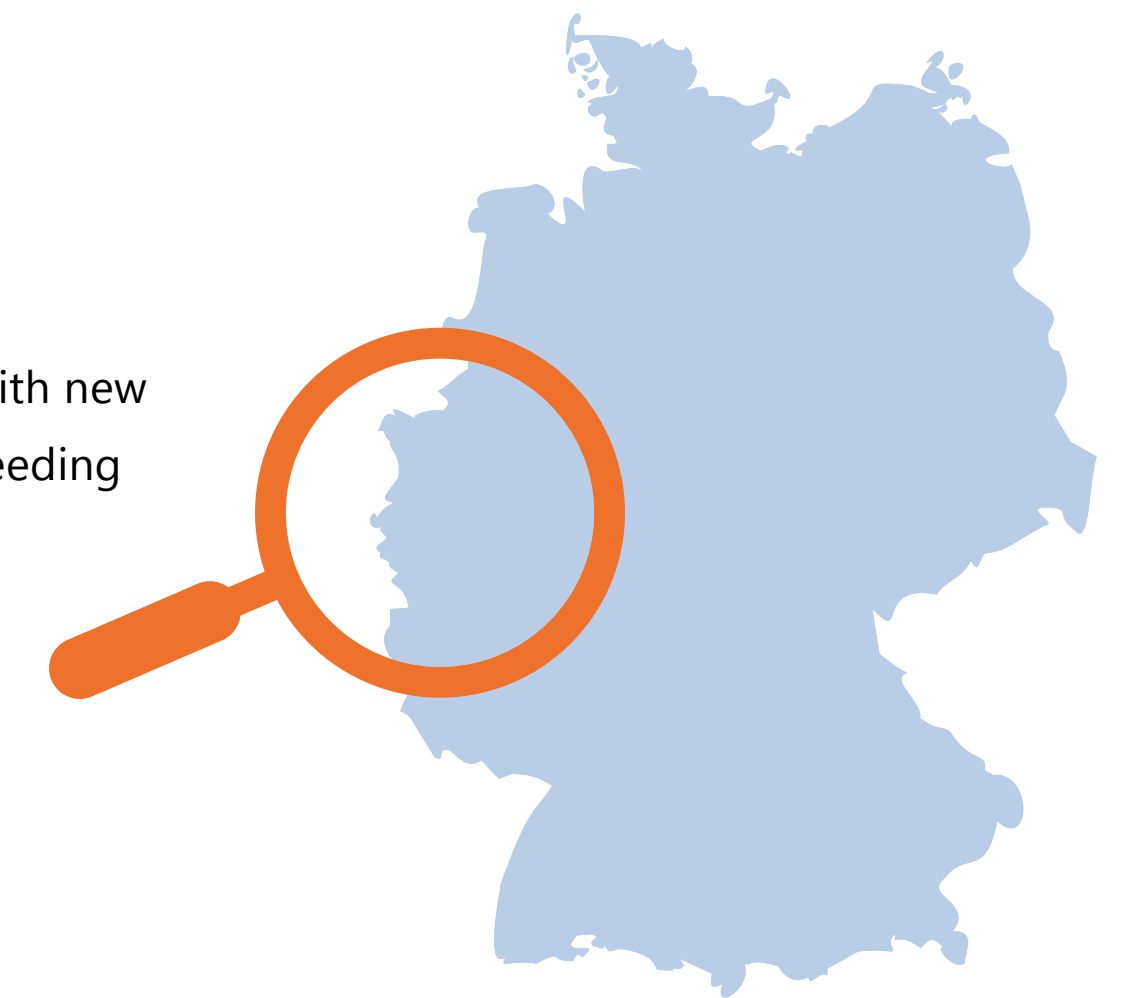
3. Age distribution of German donors



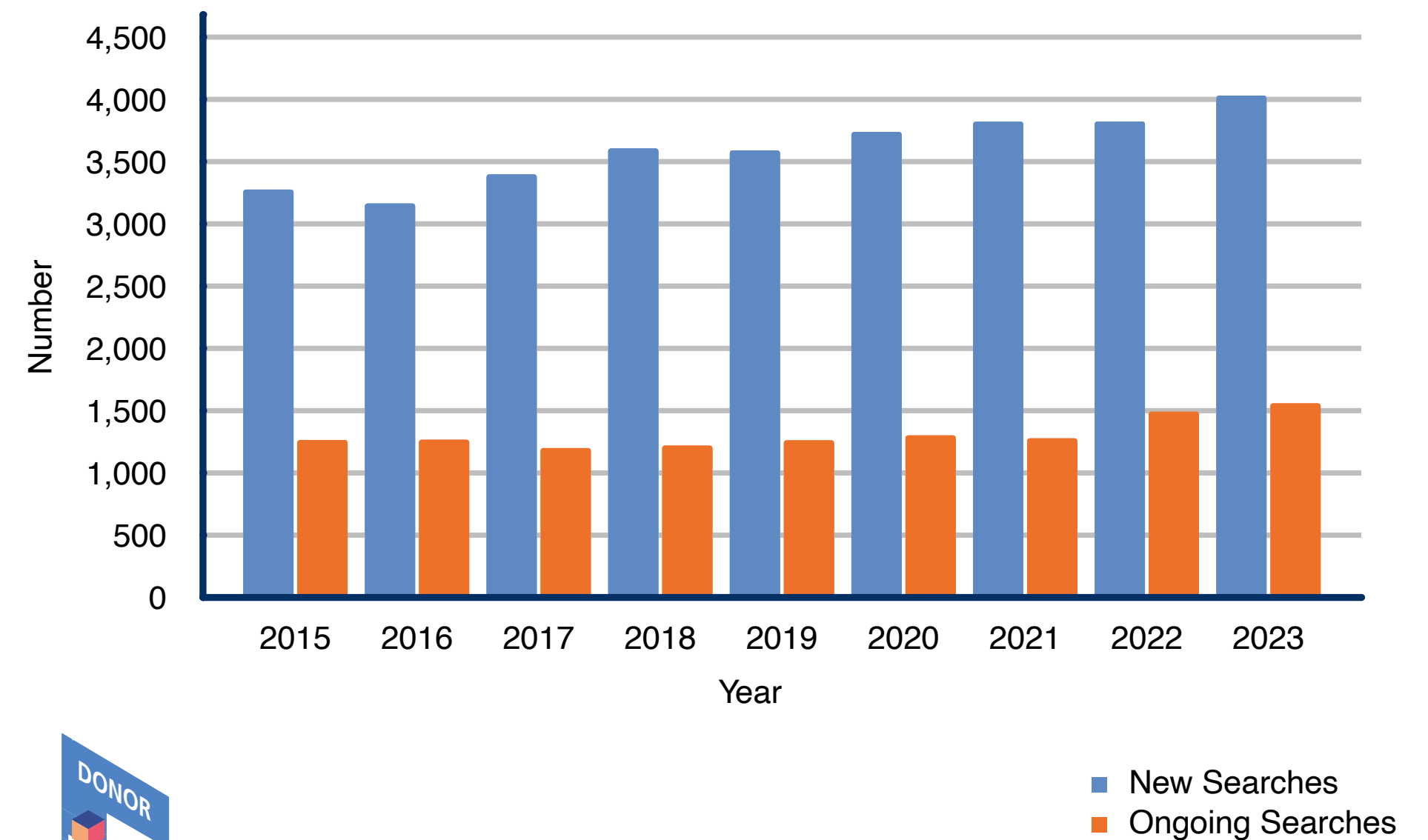
4. Age distribution of newly recruited donors



Another record was set in 2023, with new searches for German patients exceeding **4,000.**



5. Donor searches for German patients



7 The ZKRD 2023 in figures

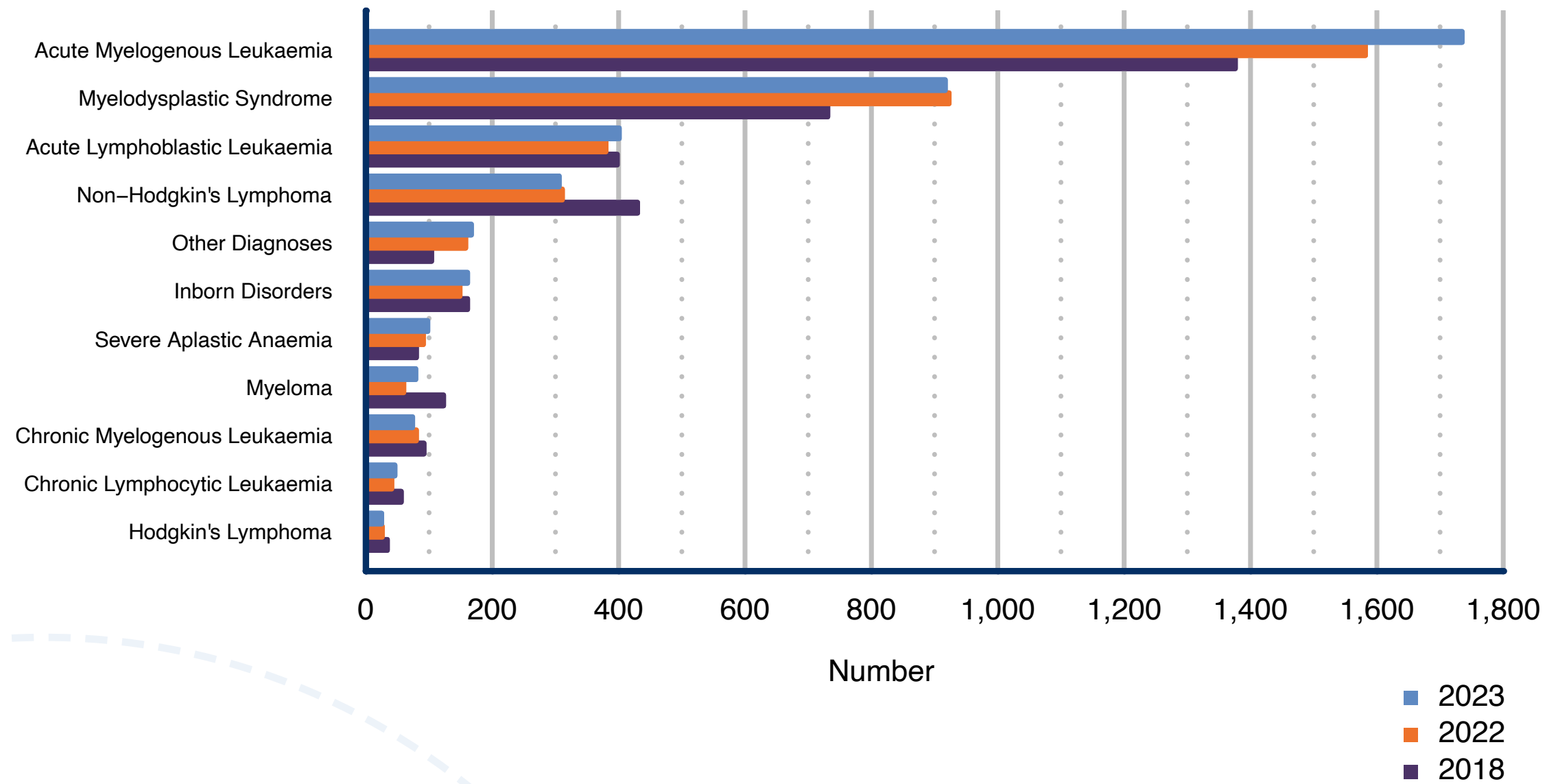
Diagnoses of AML, MDS and ALL remained at a high level in 2023, while severe aplastic anemia reached a new peak. Among German patients, the number of diagnoses increased across all age groups – with the exception of 21 to 40-year-olds – the highest increase was noted in patients over 51 years of age.



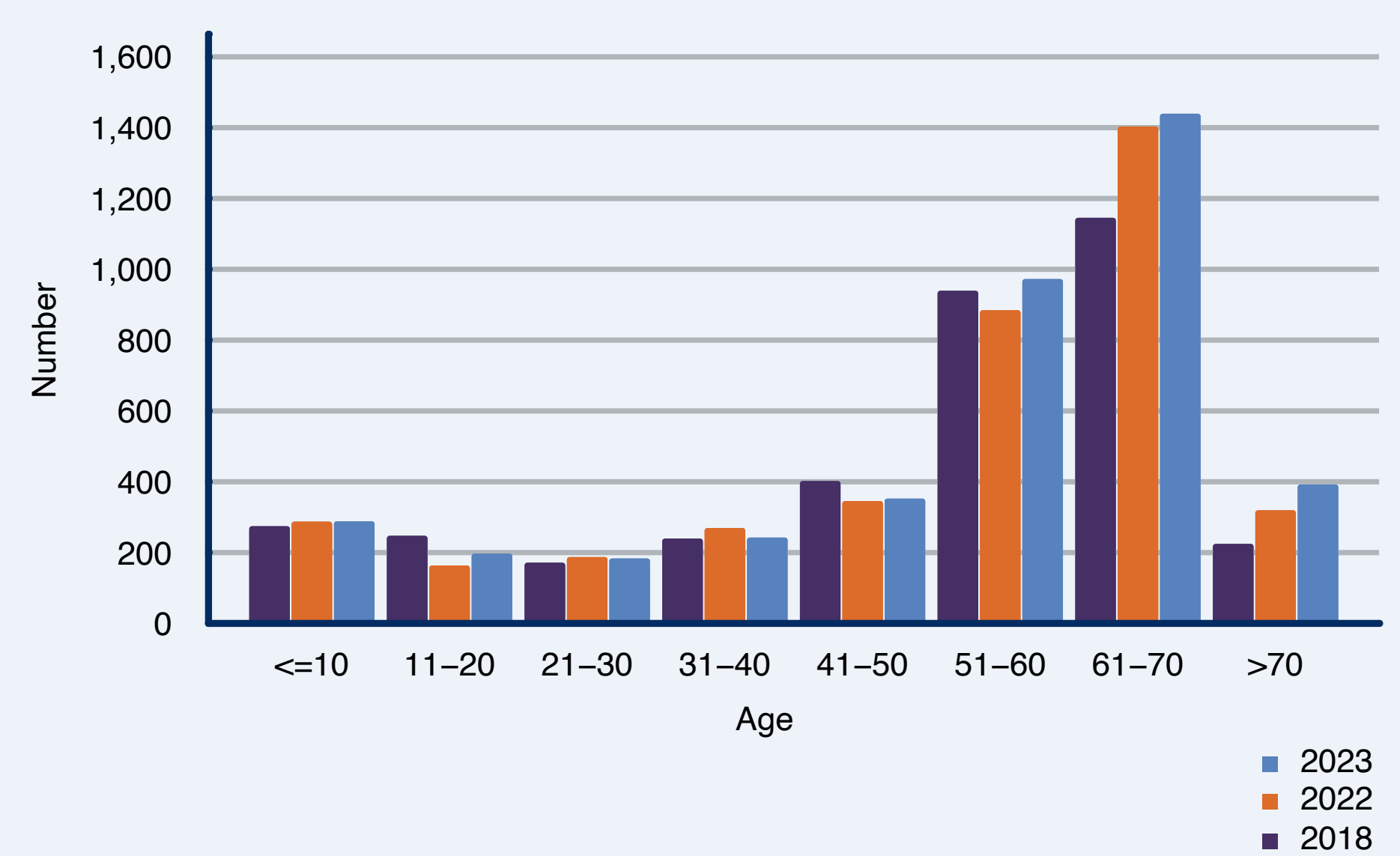
Roughly every 40 minutes, someone in Germany develops leukemia. Only in about one in four people, a stem cell donation from a family member is possible. The Central Bone Marrow Donor Registry in Germany therefore offers a lifeline to all other patients, as a transplant can be performed in about 90 percent of the remaining cases.

Daniel Günther, Minister-President of Schleswig-Holstein

6. Distribution of diagnoses among German patients

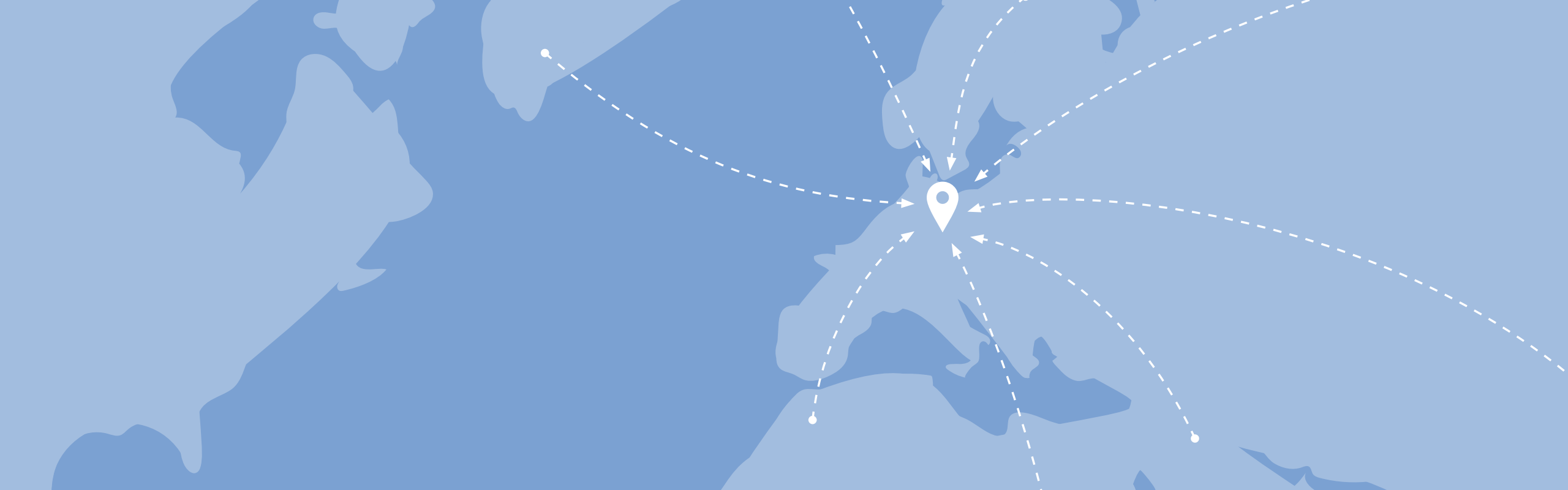


7. Age distribution of German patients

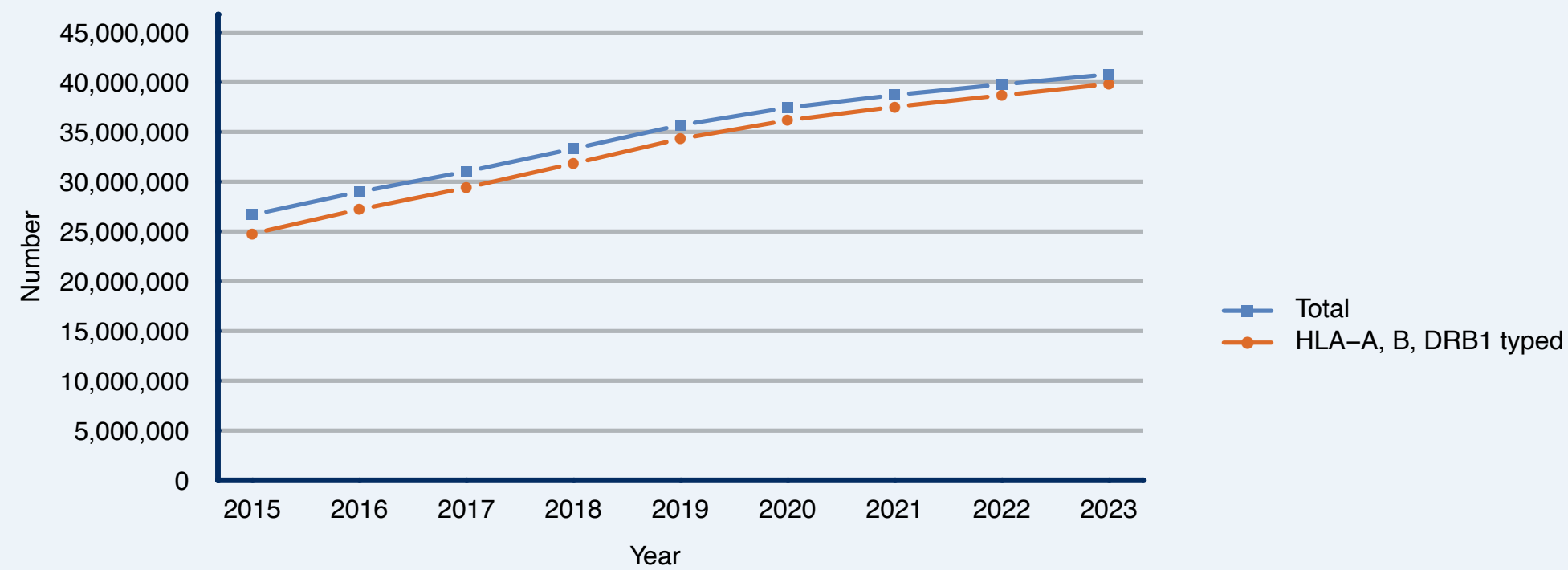


7 The ZKRD 2023 in figures

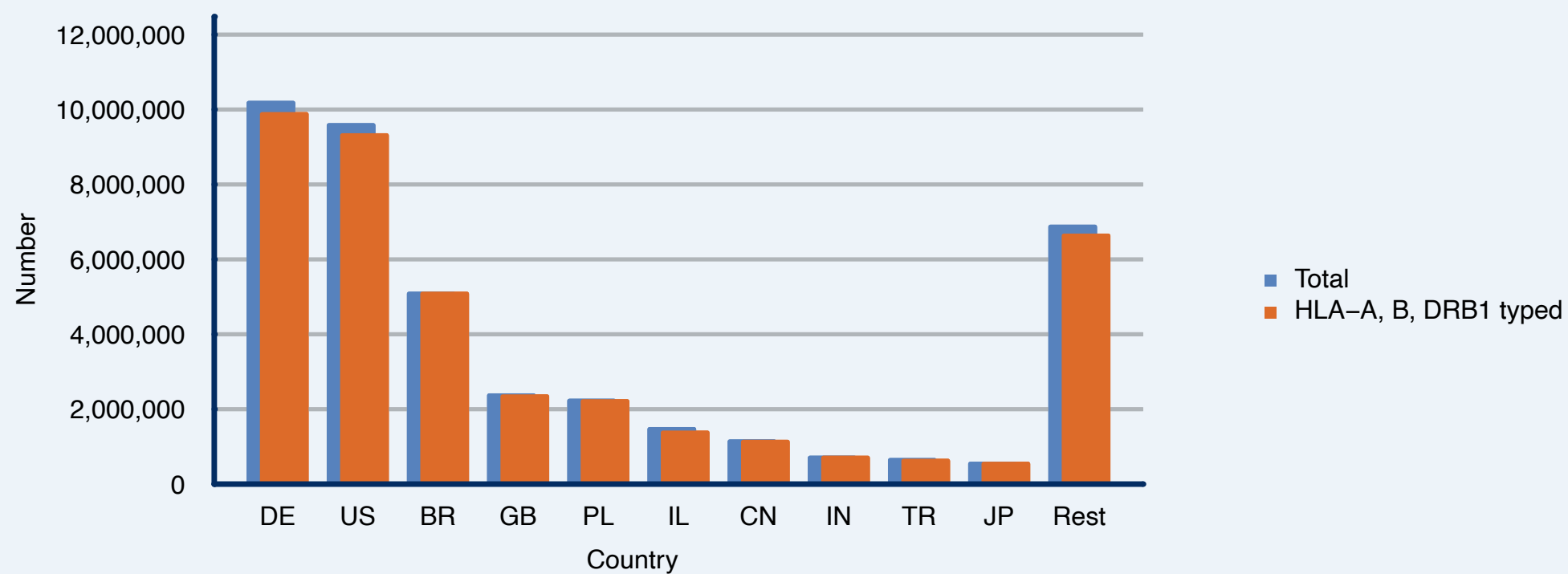
In 2023, around **one million new donors** were added to databases worldwide. Of these newly registered donors, approx. 28.2% were recruited in Germany, followed by the USA with almost 10.5%. In total, **almost 25% of the donors on file worldwide are registered in Germany.** With more than **32,000 searches** in the same year, a new peak was achieved also for international patients, which corresponds to an increase of 7.5% compared to the previous year. The USA is the country with by far the largest number of requests, accounting for more than 58%.



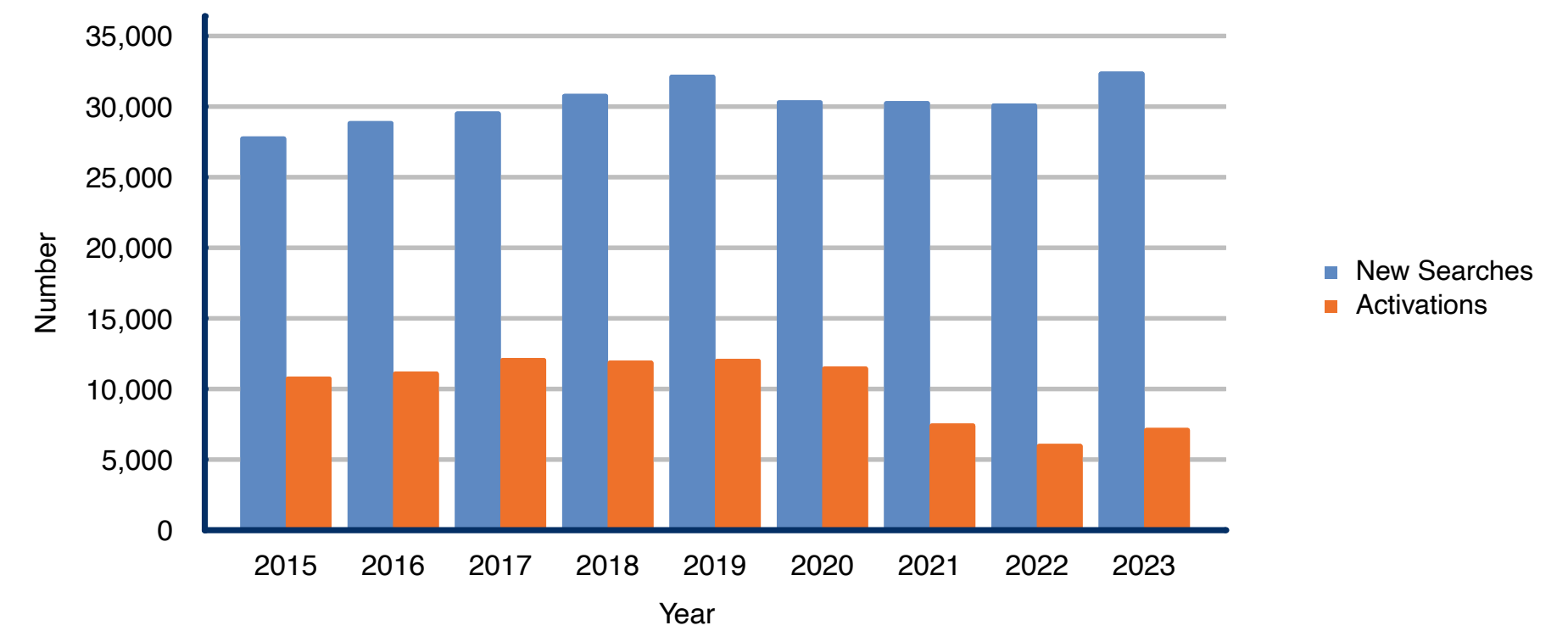
8. Donor numbers worldwide (according to WMDA)



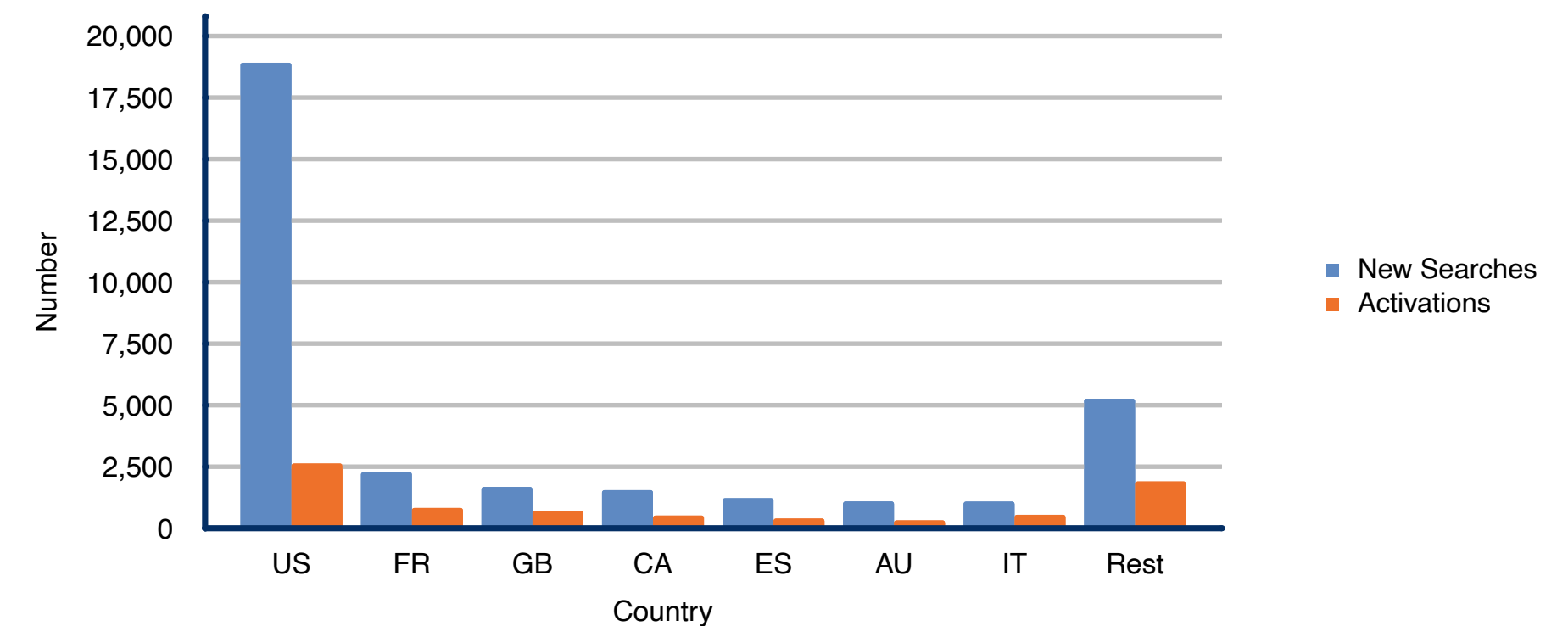
9. Distribution of donors worldwide (according to WMDA) in 2023



10. Donor searches for patients abroad



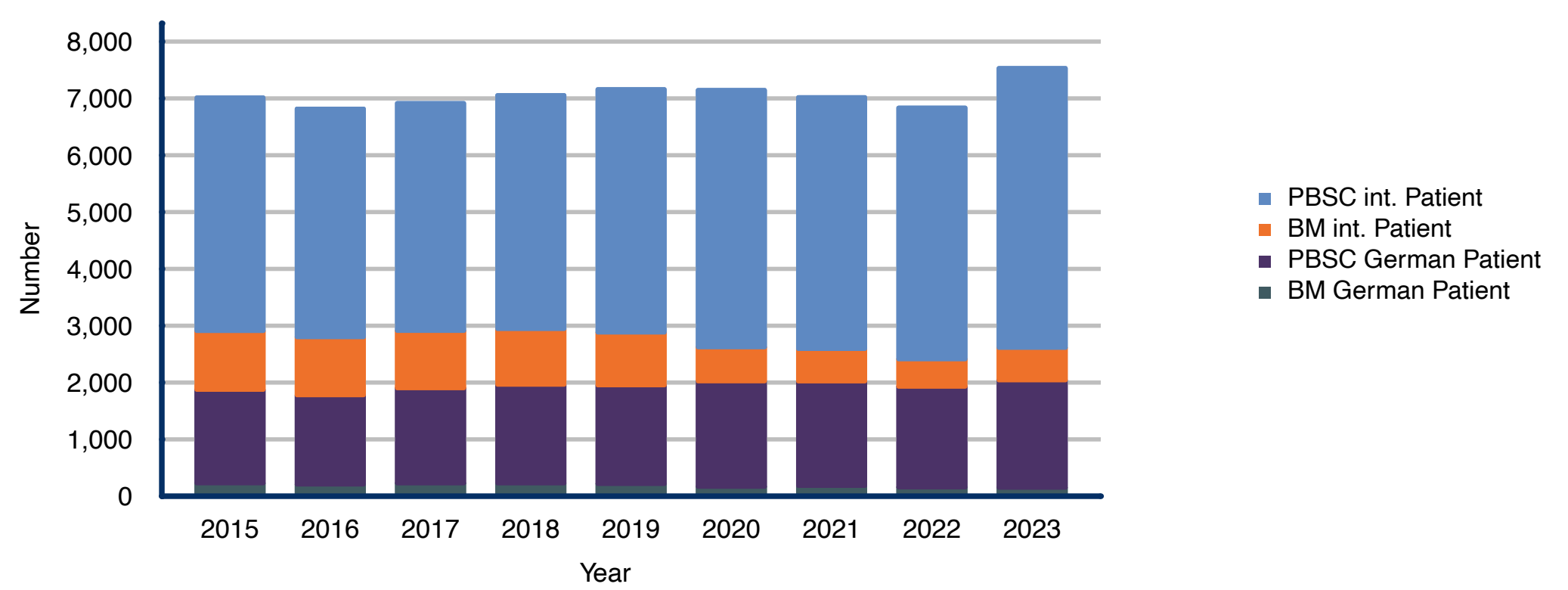
11. Origin of search requests for German donors in 2023



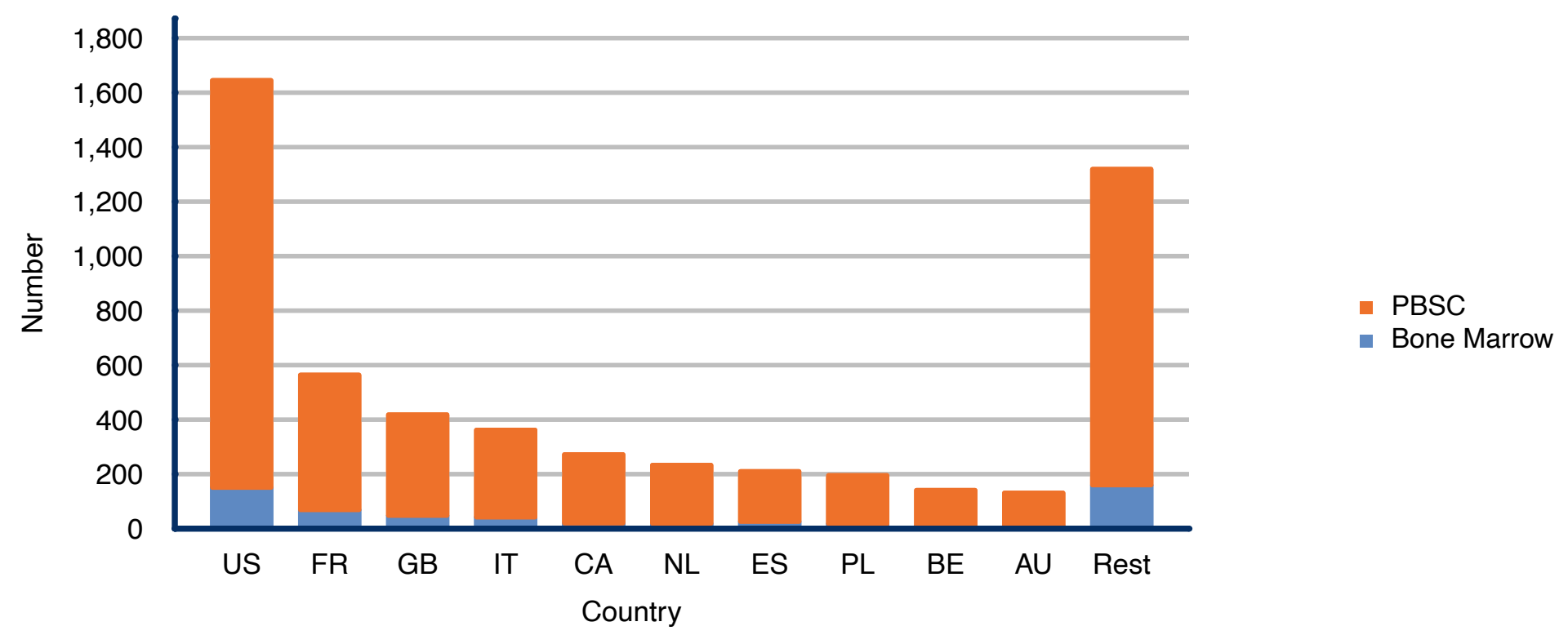
7 The ZKRD 2023 in figures

Over the past decade, the number of collections has stabilized at around 7,000. In 2023, an increase of 10% over the previous year was observed, which resulted in a record 7,532 collections – the highest since the establishment of the ZKRD.

12. Collections of blood stem cells from German donors

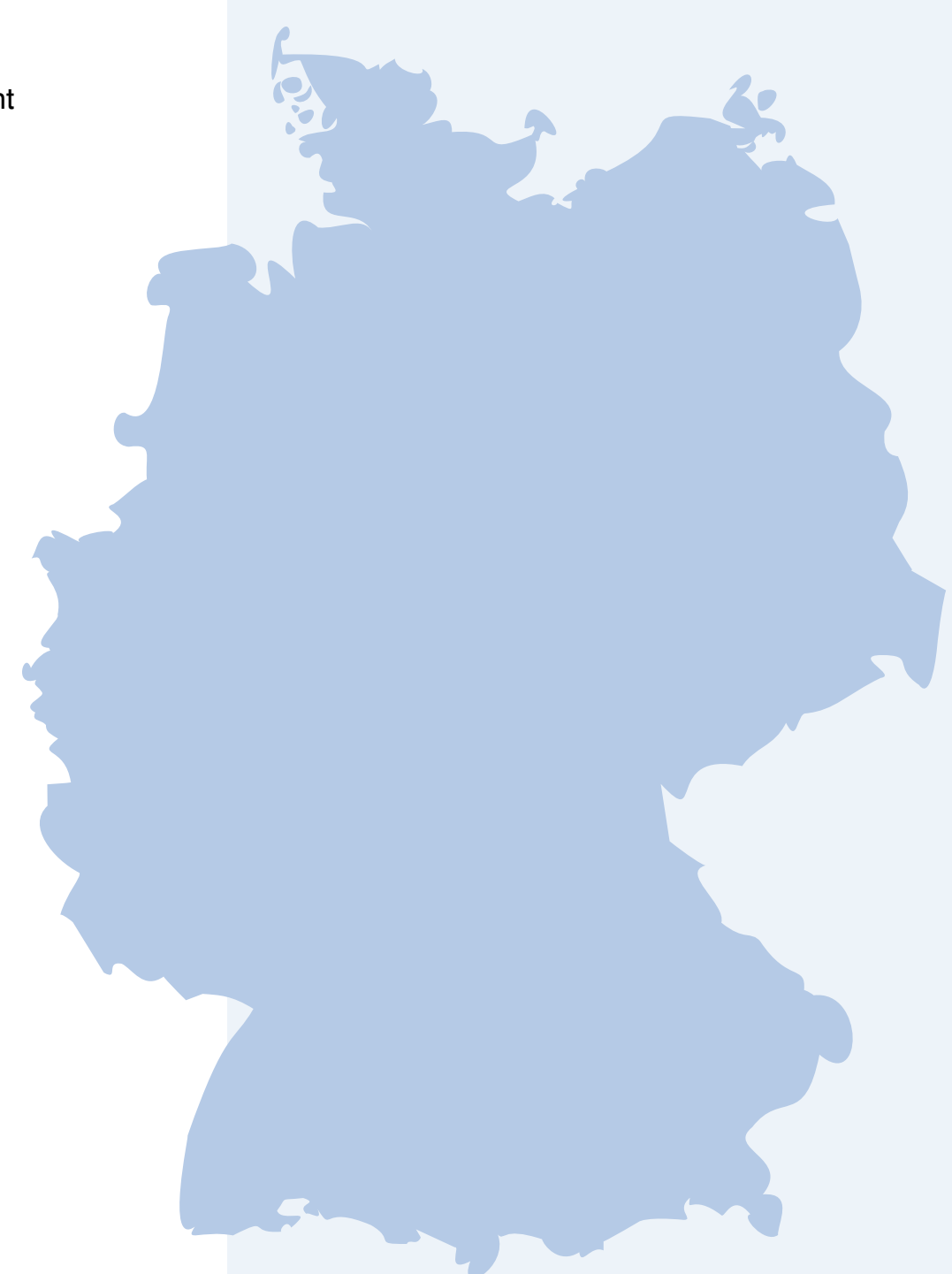


13. Distribution of stem cell collections from German donors for patients abroad in 2023



A stem cell donation is an act of selfless generosity, because for many patients, a bone marrow donation is their only chance of survival.

Karl-Josef Laumann, Minister for Labor, Health and Social Affairs of the State of North Rhine-Westphalia





ZKRD

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