nmdp BioTherapies℠
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# 6 Considerations **WHEN EVALUATING** Cell Sourcing Partners

Sourcing your starting material from healthy, high-quality donors matters when you are manufacturing an allogeneic cell therapy. Any misstep can mean delays in your therapy's development.

You don't have time for a do-over. And neither do patients.

But not every company has the deep donor pool or expertise to help you efficiently advance your therapy to market. Or can oversee, schedule and monitor collection and delivery for manufacture.

That makes choosing the right partner critically important.

We understand. Over the last 30+ years, our team has sourced and collected cells from more than 111,000 volunteer allogeneic donors for time-critical cellular therapies.

We've used what we've learned in that time to provide you with six considerations—along with questions to ask—when you're evaluating vendors to identify allogeneic donors, collect starting material and deliver the starting material for manufacture.

## 1 Donor pool depth

When your allogeneic cell therapy is in an earlier stage of clinical development, you may not need a high volume of allogeneic donors. However, your donor pool will need to grow as your therapy scales into later stage clinical trials and gains commercial approval.

By working with a partner from the start that has a large, diverse donor pool, you can quickly scale your volume. A large donor pool is particularly important when your therapy requires specific or rare donor attributes. As you add therapy-specific eligibility requirements, your pool of potential donors significacntly narrows. (Figure 1)

Partnering with an organization with a large donor base makes it more likely a donor with your specific attributes can be sourced and collected in your desired timeframe. For example, NMDP Registry℠ offers access to more than 7 million potential adult donors who are HLA typed and represent diverse segments of the population.

While repeat donations are possible if a donor is willing to participate, we do not recommend relying on a dedicated donor pool (sometimes called super donors). Doing so could introduce risk  long-term as your therapy scales.

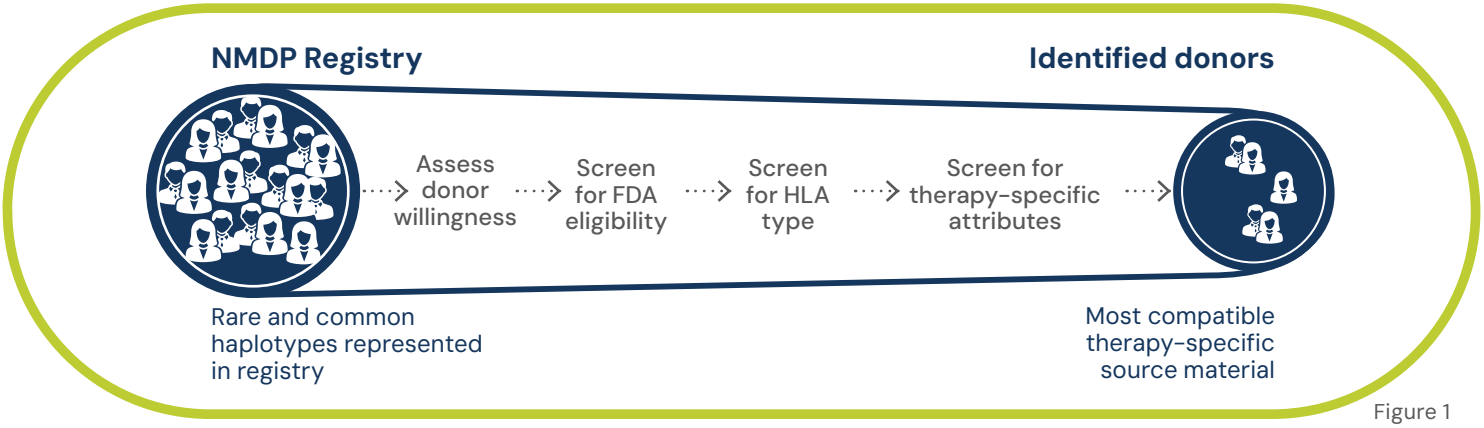


Figure 1

### When evaluating a company's donor pool depth, ask:

- What is the size of your donor pool?
- Are your donors geographically distributed or local to one city or region?
- Do you have HLA type information available? To what resolution?
- Do you have race and ethnicity information about your donors?
- Do you have, or can you obtain, a donor's serostatus for infectious diseases, such as CMV or EBV?
- How often does your company rely on repeat donors? What is the average number of times you are able to get a donor to repeat donations?

## 2 Scientific expertise

An experienced bioinformatics team can help your company determine the attributes that are the most important for your therapy and the size of the donor pool you'll need. In addition, they can help you identify compatible donors that meet your criteria.

For example, our Bioinformatics team develops software and analytical methods used to predict factors that can impact outcomes for patients who receive an allogeneic cell therapy. They assist clients with strategies to reduce the complexities of HLA matching and maximize population coverage for a cell bank.

### When considering a company's scientific expertise, ask:

- Do you have experience evaluating potential donor matching requirements to increase therapeutic success?
- Can you help determine the population frequencies for the donor attributes needed for my therapy?
- Can you help in matching the ideal manufactured cell bank to each patient?
- Can you tell me about some of the strategies your organization has developed to reduce the complexities of HLA matching inherent to allogeneic therapies?

## 3 Donor pool quality

A quality donor is one who accurately answers the health history questionnaire and shows up for exams and collection on the agreed upon dates.

If donors do not accurately portray their health history, the starting material might not be usable if issues are detected after donation. Donors who don't show up for collection can cost you your manufacturing slot, delaying the manufacture of your therapy and your path to commercialization.

When donors are donating for altruistic reasons, our experience shows that they have a higher likelihood of accurate health history reporting and showing up to scheduled appointments—including collection.

For example, through NMDP℠, we've facilitated more than 111,000 cell collections for time-critical cellular therapies. Our volunteer allogeneic donors are not compensated for their donated product or time. They receive an extensive health history screening and education. No-shows on collection day are extremely rare.

It is important to consider that cellular material collected from compensated donors may not be usable for final drug products intended for market in some developed countries. The European Union, Canada and Japan either strongly emphasize or require the use of voluntary, unpaid donors for cellular therapies.

### Ask potential cell sourcing partners:

- What is your donor no-show rate (i.e., not showing up for appointments or collection)?
- Do you compensate your donors in any way (i.e., for their donated product or their time)?
- Do your company policies meet EU regulations for compensation of donors?

## 4 Donor screening process

Collecting quality source material requires an extensive donor consent, screening and testing process. This process is necessary to make sure each donor is willing, safe and suitable to donate for your specific therapy.

A robust donor consent, screening and testing process spans from the initiation of donor contact to infectious disease marker (IDM) testing post-donation and meets FDA and international requirements for research, clinical and commercial uses.

This is an example of the multi-step process our NMDP BioTherapies[SM] team uses for each donor. (Figure 2)

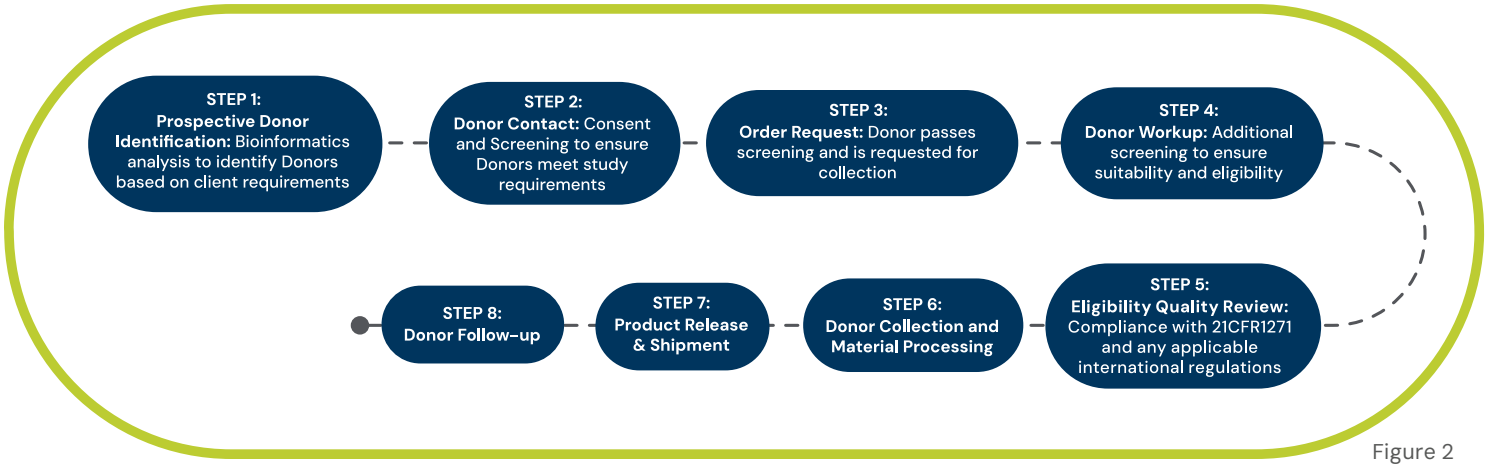


Figure 2

### When selecting a partner to source donors for starting material collection, ask:

- How will you identify and contact donors regarding this opportunity to donate?
- What is your process for consenting donors?
- Can you perform testing for infectious diseases outside of regulatory requirements for tissue (e.g., HHV 6/7/8, adenovirus, etc.)?
- Can we provide additional therapy-specific screening criteria outside of the normal screening criteria your company uses?
- How do you educate donors about therapy-specific donations?

## 5 Cell collection network depth

You need to know the centers you select to collect starting material can deliver high-quality product. Not every apheresis or marrow collection center is the same, and qualifying, auditing and onboarding each separately takes significant time and resources.

Partnering with an organization with an extensive, geographically diverse cell collection network that has implemented best practices and optimized protocols can help ensure starting material consistency.

For example, our Collection Network of 82 apheresis centers and 64 marrow collection centers across the U.S. was built over 30 years. That allows our team to partner with clients developing cell therapies to fully understand their individual therapy and regulatory compliance requirements and align collection procedures with best practices.

We determine the best-suited collection centers and provide extensive onboarding, training, and ongoing support and management for more consistent and high-quality collections. Additionally, with our large network of centers located throughout the U.S., we can grow the number of centers collecting for your product as your volumes expand.

### When selecting a partner to collect your starting material, ask:

- How many collection facilities do you have in your network?
- Are your collection facilities geographically distributed across the country or central to one region?
- How do you train your collection facilities to meet the requirements of our protocol?
- How do you ensure your collection facilities collect high-quality products?
- Are your collection centers FACT and/or AABB-accredited?
- Has your organization collected starting material to support U.S. and European-based cell therapy developers?

## 6 Logistics experience

Speed of delivery after collection is critical to cell viability. Cellular starting material must be delivered where it needs to go, when it is expected to get there, and in the required condition and temperature.

When that starting material is traveling hundreds or thousands of miles to a manufacturing facility, unexpected disruptions will occur. Working with a partner that is skilled at overcoming these challenges, and has the established relationships and contingency plans to do so, is a critical part of your therapy's success.

Our more than 65-person Cell Therapy Supply Chain Management and Logistics team has seen the importance experience brings. They've been coordinating logistics for a time-sensitive cell therapy, hematopoietic stem cell transplant, for decades—successfully delivering product within the continental United States in 48 hours or less, and internationally, barring force majeure, in 72 hours or less.

The team has learned to successfully overcome common challenges, such as weather delays. They also have the relationships in place to mitigate less common challenges, like customs complexities or disruptive world events such as the COVID-19 pandemic.

In fact, when COVID-19 shut down international borders and flights to and from the U.S. were reduced by more than 80%, our team's long-standing relationships and innovative problem-solving allowed us to continue to deliver life-saving cell therapies globally every day.

### When selecting a logistics partner, ask:

- How many years of experience does your organization have providing logistics to cell and gene therapy developers?
- How large is the team that will support the logistics activities for our product? Who are the team members?
- How many cellular therapy product shipments a year do you manage?
- How often do your shipments cross international borders? What processes do you have in place to overcome border-crossing issues for cell-based products?
- Does your company provide after-hours, weekend and holiday on-call support to manage unexpected changes and emergencies?
- What is your company's experience managing the transport of fresh products? Cryopreserved products?
- What experience does your company have providing a high-touch service, such as a hand-carried courier delivery?

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# Access allogeneic source material **YOU CAN COUNT ON.**

Over the last 30+ years, we've identified allogeneic donors for patients in need of a life-saving cellular therapy, collected their cells and delivered those cells to waiting patients around the world.

We've done so by developing the world's most diverse volunteer donor registry, unparalleled scientific expertise, an expansive apheresis and marrow cell collection network, and a logistics team experienced in overcoming unexpected challenges in the U.S. and abroad.

Connect with us to discover how you can rely on our team to minimize your risk and deliver high-quality source material to you the first time.

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NP21514; FEB 2024