

# How CIBMTR® Bioinformatics Consulting helped an allogeneic cell therapy client design an off-the-shelf cell bank

## SITUATION

A Be The Match BioTherapies® client was like many allogeneic cell and gene therapy developers. It was developing a therapy for a blood condition and needed to build an off-the-shelf bank of cryopreserved cell sources.

The client wanted to model the size and utilization pattern of a cell bank that would meet patient needs in the United States. The cell bank inventory needed to cover 90% of the human leukocyte antigen (HLA) of U.S. patients when allowing for mismatch stringencies of up to 1 of 10.

Then, it needed to build a utilization model for the cell bank. The model would be based on one-to-many donor-patient utilization established on the genotypes estimated from the development of the coverage model.

The client could not meet these objectives without knowledge of the population HLA data and modeling capabilities based on the mismatch stringencies.

## SOLUTION

The client turned to the CIBMTR Bioinformatics Consulting experts at Be The Match BioTherapies to model the size and utilization pattern of its off-the-shelf cell bank.

### Off-the-shelf cell bank coverage for U.S. patients

The CIBMTR Bioinformatics Consulting team used previously estimated and published HLA haplotype frequencies for multiple populations in the U.S. This allowed the team to estimate the optimal inventory size for cryopreserved manufactured cell sources that could service 90% of U.S. patients.

The model incorporated multiple HLA donor and patient match scenarios. For example, the scenarios included a full 10 of 10 HLA match and multiple mismatch scenarios, such as matching on Class 1 HLA genes only.



## GOALS

The client needed to understand:

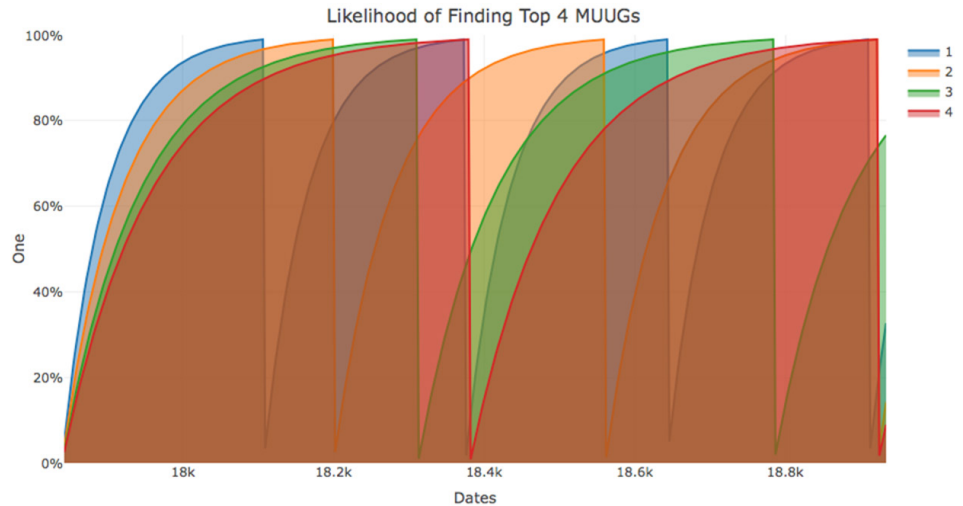
- HLA genotypes to cover most patients in the U.S.
- How many patients would be covered by cells from a single donor
- Frequency of patient requests for the therapy
- How often the cell bank should be restocked
- Genotypes that would need to be restocked
- If some genotypes would need to be restocked more frequently than others

# SOLUTION (continued)

## Restocking and utilization pattern of model cell bank

The CIBMTR Bioinformatics Consulting team estimated a model to simulate cell bank utilization and restocking frequency based on use. The team based its estimates on a one-to-many donor/patient service model along with patient HLA genotype frequencies in the U.S.

The model provides an assumed utilization scenario for the top 100 stocked genotypes and restocking frequency requirements based on the utilization scenario. The figure below shows the projected restocking pattern for four topmost common stocked genotypes (MUUG – Multi-locus Unphased Unambiguous Genotype).



## RESULTS

The estimated models helped the client efficiently plan for the size and cost of an off-the-shelf cell bank that would deliver the therapy to patients in a timely manner. The models helped streamline therapy manufacturing and delivery.

In addition, the client can use the models to develop the restocking schedule. This will allow the client to plan for the anticipated throughput to avoid the time and cost of delayed restocking.

The client is now working with Be The Match BioTherapies for cell sourcing, which can be done with more accuracy and precision because of the insights provided. Together, they are devising a plan for building, restocking and optimizing the cell bank.

## Bioinformatics Consulting for Cell and Gene Therapy

Our team's data and analytical expertise helps you define your targets and build your allogeneic off-the-shelf cell bank. Our insights are powered by the partnership of Be The Match BioTherapies and the CIBMTR.

Working with our team gives your company access to unique and expansive clinical outcomes, CIBMTR data and donor registry databases available only through our organization. You'll receive insightful data analytics and modeling based on decades of cell therapy research.

**Connect with our team:**

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