

BUILDING TOWARD INSTITUTIONAL PREPAREDNESS^{1,2}

Research into potential gene therapies for a range of conditions is ongoing. Institutions evaluating their interest and preparedness for any of these gene therapies may benefit from multidisciplinary partnerships and comprehensive process development. Identifying the right processes and champions in gene therapy preparedness may take time and may vary depending on the provider, institution, and potential gene therapy products. Timely and proactive exploration of institutional protocols may make the implementation process easier and more effective.

Note that any potential therapy will have its own specific attributes and requirements. The following content does not provide requirements or guidance for any specific gene therapies; rather, it provides general information for your evaluation and consideration. No gene therapies for hemophilia A or B have been approved for use or determined to be safe or



PREPPING THE LAND

Set the Foundation for Gene Therapies to

Various stakeholders across an institution will need to be equipped with practical knowledge about gene therapies as they become commercially available.

Once the stakeholders are identified, they will make up the **Multidisciplinary Team**

- ❑ Identify potential members of the multidisciplinary team
- ❑ Identify potential champions who can help manage, motivate, and encourage the rest of the multidisciplinary team

Champion(s) in gene therapy preparedness may be needed to:

- Align stakeholders
- Provide access to necessary information
- Help develop new institutional procedures or protocols

Potential Stakeholders



Nurse Practitioner



Care Coordinator



Social Worker



Infusion Nurse



Physician



Pharmacist



Occupational Health Services



Bioethics



Environmental Safety/Waste Management



PREPPING THE LAND

Educational Topics to Explore³

Gene therapy, from the basics to the molecular biology principles

How to educate healthcare professionals, patients, and caregivers about gene therapy

Potential outcomes

Which diseases are being investigated for gene therapy treatment

Patient perspectives on gene therapy

Properties of different therapeutic vectors and subsequently their safety and efficacy data

- ❑ Be aware of the logistics of handling each gene therapy product, from pharmacy aspects to the treatment center

Other considerations for your institution:

Empty rectangular box for additional considerations.



ESTABLISHING THE STRUCTURE

Site Preparedness^{1,2}

Given the uniqueness of gene therapy as a potential treatment and significant need for coordination, the **Multidisciplinary Team** will need time to conduct relevant conversations and develop appropriate processes

Various committees, stakeholders, and standard operating procedures will help shape your institution's readiness for providing gene therapies

- ❑ Determine if your institution requires input from other committees and/or administrators outside of your institution
- ❑ Collaborate with resourcing partners
- ❑ Conduct interviews with other institutions who have implemented gene therapy protocols
- ❑ Identify what you can do in your role to support patients and their families as they receive gene therapy



ESTABLISHING THE STRUCTURE

Site Preparedness^{1,2}

As conversations with key stakeholders progress, consider discussing the following topics:

01

YOU AND YOUR TEAM'S ROLE IN THE TREATMENT JOURNEY

- Will your center be designed specifically for handling gene therapies, managing infusions, and/or conducting all follow-up appointments?
- Or will you be an approved dosing site, to which patients are referred for their treatment and then return to their home treatment center for long-term monitoring and laboratory work?

02

RESOURCES, SPACE, AND PERSONNEL TO SUPPORT A PATIENT RECEIVING GENE THERAPY

- Required approvals from your Infection Control Committee and/or Bioethics Committee
- Materials available to train administration and clinical staff
- Capabilities, eg, laboratory assays, for posttreatment management
- Pharmacy staff who will be the responsible party for the receipt, storage, preparation, and dispensing of gene therapies
- Availability of staff to manage the follow-up caseload

03

DOES THE BILLING AND FINANCE DEPARTMENT HAVE DISCUSSIONS ABOUT THE RELATIONSHIPS AND COMMUNICATION CHANNELS OPEN FOR REIMBURSEMENT?

- Procurement considerations and contracts established prior to writing the prescription
- Certifications potentially required from participating physicians, infusion staff, pharmacists, etc
- Billing system updates to support accurate coding and billing procedures

Other considerations for your institution:



CLICK OR SCAN



Additional Resources

References: 1. Petrich J, et al. *J Pharm Pract* 2020;33(6):846-855. 2. Miesbach W, et al. *Haemophilia*. 2021;27:511-514. 3. Pipe SW. *Haemophilia*. 2021;27(suppl 3):114-121.

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

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