

SITE READINESS QUESTIONNAIRE

for infusion sites preparing for gene therapies



This questionnaire does not apply to any specific gene therapy. Rather, it presents general considerations common to many gene therapies based upon ongoing research. The considerations presented here are general, subject to change, and should be evaluated in light of additional guidelines, research, and potential requirements arising from other sources, including national, local, institutional, and payor requirements.

No gene therapies have been approved for hemophilia A or B and the safety and effectiveness of gene therapies for hemophilia A or B has not been established.

Hemophilia treatment center name

City

State

Site readiness lead full name

Email address

Telephone number

QUESTIONNAIRE SECTIONS

Hello, and welcome to the Site Readiness Questionnaire for infusion sites preparing for gene therapies. It's important to understand that there are many different facets to consider when planning for potential gene therapies. Depending on the infusion site and situation, many people may be involved in the steps detailed here. This survey is designed to give you an idea of what questions your infusion site may need to consider, especially if you have no experience with gene therapy treatments.

CLINICAL CONSIDERATIONS 4

Gene Therapy Education	4
Patient ID/Preparation for GT	5
GT Communication/Referral Process/Follow-Up	6
Infusion Suite Logistics	7
Infusion Suite Staffing	8

PHARMACY AND PRODUCT CONSIDERATIONS 9

Standard Operating Procedures	9
Pharmacy Staffing	10
Institutional Guidelines	11
Product Handling	12

OPERATIONS AND REIMBURSEMENT CONSIDERATIONS 14

Payer Implications	14
Distribution/Product Acquisition	15

EVALUATION KEY

At the end of this questionnaire, please assess the appropriate readiness status of your infusion site.

