ASGCT and FDA Liaison Meeting

February 23, 2024
1:30-3:30 PM ET

American Society of Gene + Cell Therapy

CDRP Feedback

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ASGCT Feedback on the CMC Development and Readiness Pilot (CDRP)

How was the feedback obtained?

ASGCT conducted a voluntary, anonymous survey.

Feedback is based on a small sample size (short turnaround time, newness or awareness of the program).

What was the feedback?

<u>Participation is difficult due to very narrow eligibility criteria.</u>

- CBER requirement for Breakthrough or RMAT designation is extremely limiting and excludes many programs that may want to participate. Many other programs with novel technologies or serving unmet needs may benefit.
- *ASGCT encourages the Agency to consider if the requirement for BTD or RMAT can be eliminated.*

<u>Uncertainty exists around potential for public data sharing.</u>

- ASGCT supports data sharing (with consent) to improve transparency within the industry. However, it is not clear what will be disclosed as an outcome of participation in the pilot.
- *ASGCT suggests CBER provide additional clarity around disclosure requirements. One suggestion related to data sharing was to offer a phased approach where sponsors control the scope and timing of information sharing, starting with less sensitive details and increasing disclosure based on program progress. This could balance FDA's need for insights with sponsor concerns.*

<u>Benefits of the program are unclear.</u>

- Additional benefits beyond RMAT/BTD are unclear. Also, additional meetings does not necessarily result in improved collaboration and there may be a fear that participation may only invite increased scrutiny.
- *ASGCT members suggest CBER provide greater clarity around the benefits a sponsor could expect with the program.*

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