



Expanded Access Working Group ESP Leadership Development Program

a) Scope and research interests

The Working Group aims to identify and address practical, ethical, and regulatory issues that arise from the use, and potential misuse, of the US expanded access pathway by various CGT stakeholders. The Working Group develops informed perspectives on expanded access to generate educational resources that promote innovation in translational research while upholding the highest ethical standards.

b) Projects and responsibilities for the ESP member

The ESP member will participate as a full voting member of the Working Group and engage and collaborate in project tasks and assignments with other members and teams as they arise.

In addition, the ESP member may be asked to contribute to the following projects:

- Develop Telegraft feature on use of US expanded access programs within CGT space and role that ISCT is playing in developing code of ethics to encourage best practices
- Maintain and update database of CGT expanded access programs in the US
- Attend ISCT 2023 Paris Annual Meeting and support Working Group activities
 - Collaborate with ESP Member on Committee on the Ethics of Cell and Gene Therapy (ECGT) to contribute section to ISCT 2023 Proceedings Paper
 - Attend Expanded Access Roundtable and draft session summary and key takeaways
- Participate in other ISCT Annual and Regional Meetings and contribute to Working Group activities as they arise
- Lead drafting of a section of the expanded access code of ethics relevant to ESP Member's interests and expertise

c) ESP member's opportunities within the Working Group

Connect and collaborate with KOLs and SMEs within and outside ISCT to develop informed and measured positions that provide clarity and direction for the CGT field in the US. Participate in development of standard setting code of ethics for the use of US expanded access pathway for CGT products. Other specific opportunities.

[Committee Webpage](#)