

## Concept note for inclusion into a consortium into the call: HORIZON-HLTH-2026-01-TOOL-07: Establishing a European network of Centres of Excellence (CoEs) for Advanced Therapies Medicinal Products (ATMPs))

The proposed contribution of CTGCT to the *HORIZON-HLTH-2026-01-TOOL-07* project is built around the development and pilot demonstration of the “**EU-ATMP Bridge**” model, aimed at accelerating the integration of emerging translational centres into the European network of Centres of Excellence (CoEs) for Advanced Therapy Medicinal Products (ATMPs). The concept is based on the recognition that, while Europe hosts outstanding scientific excellence, the pathway from academic discovery to clinical application is often fragmented due to a lack of intermediate translational capacities, particularly in countries with less developed ATMP infrastructure. In this context, CTGCT positions itself as a pilot example of a new generation translational centre that systematically fills the gap between research laboratories and highly specialised GMP manufacturing facilities within the European CoE ecosystem.

A central element of the concept is the development of a **European framework for assessing the translational maturity of ATMP technologies**, enabling structured evaluation of how close a given therapy is to entering the clinical phase. In collaboration with partners across the network, CTGCT would help establish a methodology to identify key scientific, technological, regulatory, and manufacturing gaps, and to provide a practical tool that supports researchers and small innovation teams in understanding the next steps on the path to patients. Such a framework would also facilitate more efficient matching of projects with the most suitable Centres of Excellence across Europe, thereby strengthening cross-border collaboration and reducing duplication of effort.

Within this framework, CTGCT proposes the implementation of “**Bridge Labs**” — translational laboratories designed to operate as a functional bridge between academic research and full GMP production. These laboratories would develop and apply standardized, quality-controlled procedures for the optimisation of cell and gene therapy prototypes, preparation of technical documentation, and early process validation before transfer to larger, fully certified manufacturing centres. In doing so, CTGCT would demonstrate how emerging or smaller infrastructures can make a meaningful and complementary contribution to the European ATMP ecosystem without duplicating existing large-scale capacities.

An additional key component of the concept is the establishment of a **clinician-driven translational model**, in which innovation pathways originate from clearly defined medical needs. In close collaboration with physicians and clinical institutions, CTGCT would help set up structured mechanisms for translating clinical challenges into research and technology development projects in the ATMP field. This approach ensures that research priorities are closely aligned with real patient and healthcare system needs, while also providing the CoE network with a continuous pipeline of clinically relevant projects with strong potential for progression into advanced clinical studies.

The concept further includes a strong component dedicated to **training, mobility, and knowledge transfer**, aimed at strengthening capacities in regions where ATMP development is still emerging. CTGCT would contribute to the design of exchange programmes for researchers, short-term specialised training, and hands-on workshops covering translational development, regulatory pathways, and quality standards. This would support the emergence of a new generation of professionals capable of navigating the full lifecycle of advanced therapies, from biological concept to clinical implementation.

Through this comprehensive approach, CTGCT would act as a demonstration hub showing how excellence in advanced therapies can be expanded geographically and institutionally across Europe. The “EU-ATMP Bridge” concept therefore represents not only the contribution of a single institution, but also a scalable model for systematically integrating new actors into the European ATMP ecosystem, with the ultimate goal of shortening the path from laboratory to patient and strengthening Europe’s long-term competitiveness and resilience in advanced therapies.