



Accelerating Development and Improving Access to CAR and TCR-engineered T cell therapy (T2EVOLVE)

Accelerating development and increasing awareness and access of patients with cancer to immunotherapy



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1. Describe your project through three key words / key phrases that identify it.

The vision of T2EVOLVE is to build a sustainable innovation ecosystem that will support the development of advanced engineered T cell therapy to a level where every European cancer patient in need has access to safe and effective (curative) T cell products.

2. In terms of impact, what are the most concrete results your project has or will achieve?

The T2EVOLVE project will significantly impact the R&D process, enhancing the development of safer and more effective engineered T cell therapies. By optimizing preclinical models, analytical monitoring, and lymphodepletion regimens, the project will reduce toxicity observed in clinical trials and improve efficacy prediction, thus increasing the success rate of clinical trials. Standardizing safety and efficacy testing, manufacturing, and monitoring will accelerate clinical translation, making Europe a more competitive ecosystem for T cell therapy development. The project will also facilitate the establishment of clinical networks for studies on new therapies. Through collaboration with regulatory agencies, SME partners will gain a competitive advantage. Moreover, patient stakeholder involvement will ensure consideration of patient perspectives in therapy development.

The project will impact healthcare practices by increasing awareness among healthcare professionals (HCPs) of patient concerns through educational materials and tools. It will improve patient access to therapies by enhancing all aspects of access, including availability, affordability, and accessibility, through standardized manufacturing processes and education initiatives. Additionally, the project will accelerate the development of allogeneic T-cell therapies and increase HCP and public awareness through various outreach efforts. Combining public and private funds will ensure the deployment of developed standards and tools across industry partners, facilitating collaboration and joint publications. Overall, the project's success will be measured by regulatory acceptance of standards and methods, increased industrial competitiveness, improved access to therapies, and enhanced awareness among stakeholders.

3. Please describe your project overall impact at the European level

The T2EVOLVE project will have a profound impact on the European research and development (R&D) landscape, addressing critical bottlenecks and enhancing competitiveness in the global market. By optimizing preclinical models, analytical monitoring, and lymphodepletion regimens, the project will enable the development of safer and more effective engineered T cell therapies, thus improving the success rate of clinical trials.

Standardizing safety and efficacy testing, manufacturing, and monitoring will accelerate clinical translation and incentivize biotech and pharma companies to conduct first-in-man and market approval clinical trials within the EU, fostering competitiveness on a global scale.

The project will foster the development of clinical networks capable of performing studies for new therapies, increasing industrial competitiveness by making Europe a more attractive ecosystem for development programs. Through collaboration with regulatory agencies and the embedding of patient stakeholders in the R&D process, the project will ensure consideration of patient perspectives and regulatory compliance, further enhancing industrial competitiveness.

Clinical and healthcare practices will be significantly impacted, with increased awareness among healthcare professionals (HCPs) of patient concerns and improved patient access to engineered T cell therapies. By improving all aspects of access and streamlining development processes, the project will increase affordability and positively impact the cost of development, addressing major barriers to patient access.

Furthermore, the project's impacts will be maximized through the combining of H2020 and private sector funds, facilitating interaction between public and private stakeholders and ensuring widespread deployment of developed standards and tools. This collaborative approach will lead to the acceleration of allogeneic T-cell therapies development and the opportunity to compare data generated from standardized analytical methods, further enhancing competitiveness and innovation in the European biotech and pharma sectors.

4. As an applicant, what advice would you have wanted in the Horizon project design process? What support did you receive from National Contact point (NCP) and your organisation, and what improvement of support would you benefit from?

The advice received was pertinent and appropriate and guided us to success. I believe that the most important ones could be summarized in the following points:

First and foremost, it's essential to thoroughly understand the program's objectives, priorities, and evaluation criteria. This understanding will guide the alignment of the project proposal, increasing its likelihood of success.

Engagement with stakeholders is paramount. From the project's conceptualization stage, involving relevant parties such as industry partners, academia, SMEs, regulatory bodies, and end-users fosters collaboration and ensures buy-in. This collaborative approach enriches the project's perspective and enhances its potential for impact.

A transdisciplinary approach is highly advantageous. Integrating expertise from diverse fields, including science, engineering, social sciences, and humanities, allows for a comprehensive exploration of complex challenges.

Highlighting the project's innovation and its potential socio-economic impact is crucial. Clearly articulating how the project addresses current needs and contributes to EU priorities strengthens its proposal.

Moreover, an enhanced level of support would involve having access to an up-to-date overview of ongoing projects in our field. This would facilitate the identification of potential synergies at an earlier stage of the projects. It is essential for this list to be consistently updated and readily shared with project coordinators throughout the project's lifecycle. This ensures a comprehensive understanding of the field's direction and collective efforts.

5. Besides this set of questions, please describe and highlight aspects of your project's strengths that you consider important and that may constitute good practice for other applicants.

Our project's strength lies in a dynamic core team of academic and industry leaders, scientific project managers, and a strategic program manager. This team ensures smooth coordination, fosters collaboration, and enhances communication within the consortium and with external stakeholders. They connect different work packages, find synergistic partnerships, and keep the project on track, serving as a model of efficient leadership for complex research projects. Remaining adaptable throughout the project lifecycle is crucial to address unforeseen challenges and capitalize on emerging opportunities, ensuring project success.

