The ultimate objective of THEGRAIL project aims at developing a **bioactive and bioresorbable scaffold for *in vivo* regeneration of intima layer** after any treatment leading to an atherosclerotic plaque ablation from the obstructed arteries in patients suffering from occlusive coronary or peripheral arterial diseases.

Being the primary cause of cardiovascular disease, atherosclerosis has been the focus of much research leading to rather effective treatments. Still, current therapeutic options such as bypass or angioplasty have a major shortcoming: they are mostly short term solutions, failing to restore vessel integrity and patency. Conversely, THEGRAIL technology does not intend to stent the artery; it aims to replace the diseased and stiffened area with a soft and compliant intelligent scaffold (name **Synthetic Intima Layer** – SIL) that will reabsorb once its task is completed, leaving a physiologically responsive regenerated tissue.

The invention relies on two main innovations:

INNOVATION 1:

Smart polymers based on **Elastin Like Polymers** (rELP) to produce bioactive and bioresorbable scaffolds capable to induce regeneration of intima layer *in vivo* by means of recruiting patient circulating endothelial cells and adhere to the arterial media. THEGRAIL Project is based on the use of recombinant Elastin Like Polymers (rELP) that display Inverse Temperature Transition (ITT) feature. rELP are completely water soluble under their specific transition temperature (Tt) and switch to hydrogel state when temperature is raised over Tt.

INNOVATION 2:

Conical endovascular catheter development for the deployment of the bioactive scaffold delivered as liquid and spontaneously switch *in situ* to an elastic hydrogel at body temperature.

During the five year of project, we progressed the THEGRAIL concept **from sketch to a working prototype validated in relevant environment** (TRL 5). Exhaustive systemic toxicology tests coupled with in vivo observation proved the **complete safety of the SIL gel**. Supported by exhaustive chemico-physical characterization and biosafety data, the THEGRAIL consortium is ready to enter long-term GLP efficacy study with the ultimate goal to reach first-in-human trials within 2019. Toward this end, THEGRAIL consortium started a coordinated effort to engage VC and private funds to bring the product to the market. The exploitation strategy is based on a solid IP including 2 patents (WO2015008152 and WO2014041231A1) and several technological processes that optimally place the consortium with respect to competitors.