



The sensitive structure of proteins makes the handling of protein drugs complex. Our research can change this.



Aiding in the development of more robust protein drugs and increasing safety for patients.

Many new medicines are based on proteins, which have improved the lives of people with a range of diseases. Unfortunately, proteins are sensitive, and can be affected by exposure to heat, sunlight or shaking. The development, production, distribution, and handling of this class of drugs still present challenges that need to be addressed to generate further evidence on stability, and therefore safety and efficacy during handling in use.

The RealHOPE consortium will cover in-use aspects of protein pharmaceuticals, investigating and recognising the critical steps where stability can be compromised.

With the common goal to support a safe and efficient use of these medications for patients, whose life often depend on them, we will develop concrete and practical recommendations and tools for simulation of real-life events, mitigation of critical handling steps, and education to ensure careful handling by health-care and pharmacy staff as well as patients. From this, recommendations and guidelines will result that have an immediate impact on drug development, distribution, and handling.

The RealHOPE project will:

- include measurements of real-life handling of protein drugs using smart tag technologies to log, light, temperature and shock, during transportation and handling by healthcare personnel and patients.
- will also analyse the proteins at different stages. The combined data will be used to develop new methods to simulate real-life events and thereby ensure more robust protein drugs in the future.
- will also include interviews with stakeholders, such as patients and health care personnel at hospitals and pharmacies to create a better picture on how protein drugs are being handled today and how to educate stakeholders in the future.

About the project

The RealHOPE project is a joint collaboration by a consortium of 24 partners consisting of pharmaceutical companies, instrument- and app developers and logistics companies together with universities, institutes, hospital pharmacies, pharmacists and a patient organization from 6 European countries and US. Budgeted with 7,1 M€ the project, coordinated by RISE Research Institutes of Sweden and Lund University, with Sanofi as a tech lead, will be active until June 2025.

Project goals

- RealHOPE research have gained improved understanding of real-life handling of protein drugs.
- RealHOPE have developed tools and methods for simulation of real-life events during drug product handling that mimic the effects on drug product quality.
- RealHOPE can demonstrate and/or have developed new technologies for safer handling of protein drugs at hospital pharmacies.
- RealHOPE have developed educational and training materials for healthcare providers and patient organizations/ stakeholders to improve the safety and handling of protein drug products.
- RealHOPE have made sure that findings within RealHOPE are implemented in regulatory guidelines for industry. For example, we have made medical product agencies aware of the findings within RealHOPE and they have implemented our research into their process when admitting new protein drugs to the market.

Building knowledge to ensure that a protein drug is safe and efficient during their whole life cycle.

The RealHOPE project consists of five different work packages that together will build new knowledge and find new methods to ensure product quality through the whole value chain, from the developer to the patient.

SHAPE

The first work package is called SHAPE and will gain an improved understanding of real-life handling of protein drugs. SHAPE main task is to shape the initial part of the RealHOPE project by generating, collecting, and analysing qualitative and quantitative data in real-world scenarios. The project team will analyse information from other sources as well as conduct two transportation studies with another project and external stakeholders.



GOLD

The second work package is called GOLD and will develop tools and methods for simulation of real-life events during drug product handling that mimic the effects on drug product quality. The project team will collaborate with work packages SHAPE and HIGH as well as with EFPIA partners to developing methods, guidelines, and strategies that will aid the managing of protein drugs in the real-world.



HIGH

The third work package is called HIGH and it will demonstrate and/or have develop new technologies for safer handling of protein drugs at hospital pharmacies. The project team will look at the methods and guidelines in use to improve the handling of drugs in hospital.



TEACH

The fourth work package is called TEACH and will develop educational and training materials for healthcare providers and patient organizations/stakeholders to improve the safety and handling of protein drug products.



PAGE

The fifth work package is called PAGE and evolves the project management of the project and will spread the word about the RealHOPE and the research result with the goal that new methods and techniques are implemented in regulatory guidelines for industry. For example, we have made medical product agencies aware of the findings within RealHOPE and they have implemented our research into their process when admitting new protein drugs to the market.



THE PARTNERS

Toghether we can acquire a deep understanding of the whole life chain of a protein drug.

Within RealHOPE, we have partners from the whole value-chain: including pharmaceutical companies, logistics companies, pharmacies, and a patient organization. In combination with instrument- and app developers, and academic researchers from different fields, we will have the possibility to acquire a deep understanding of the whole life-chain of a protein drug, from production to when it reaches the patient.

To see a list of all partner and visit partner websites, please go to realhope.se



Real World Handling of
Protein Drugs –
Exploration, Evaluation and Education



This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 101007939. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA companies.