



**PROPHARMA
GROUP®**

Improving Patient Health and Safety



Istituto Romagnolo per lo Studio dei Tumori "Dino
Amadori" (IRST srl)

Safety training for the handling of MOGMs

This Proposal is presented to:

ProPharma Group		IRST srl
Name	Roley Davis	Dr. Massimiliano Petrini
Title	Business Development Manager	Qualified Person
Email	roley.davis@propharmagroup.com	massimiliano.petrini@irst.emr.it
Phone	+44 75 8644 1663	+39 0543 739100
Address	Field House, Station Approach, Harlow, CM20 2FB, UK	Via Piero Maroncelli, 40 - 47014 Meldola (FC) - Italy
ProPharma Group Proposal Number		1.0
		Date
		13-10-2021

*ProPharma Group with its global Headquarter in Kansas City, covers the following subsidiaries in Europe to whom this proposal shall be deemed to be applicable.

ProPharma Group The Netherlands B.V. Chamber of Commerce in The Netherlands with number 28108787,

ProPharma Group GmbH, registered in Germany under the number HRB 121013B.

ProPharma Group Sweden Holding AB, registered in Sweden under the Org. Nr. 559083-7190.

ProPharma Group Sweden AB, registered in Sweden under the Org. Nr. 556631-3036,

and its affiliated company ProPharma Group MIS Ltd., registered in England and Wales under the Reg. Nr. 03671574

1. Corporate Profile

1.1. Company Overview

Established in 2001 ProPharma Group is a truly global, independent, single-source provider of regulatory, compliance, pharmacovigilance, and medical information services. We work in close partnership with our clients, often as an extension of their team, to improve the health and safety of their patients. We do this with an unwavering focus on delivering the highest quality services via our team of more than 1 200 full-time, qualified subject matter experts. Our ability to be nimble coupled with a passion for excellence ensures our services exceed clients' expectations.

ProPharma Group partners with life science companies to solve their complex challenges. As an extension of your team, we care about not only the progression of your products through the development lifecycle, but also the safety of your products and the patients who use them. Our staff has an array of expertise to expand your capacity and capabilities so that you can use our vast knowledge base to tailor solutions unique to your needs.

ProPharma Group provides services for all phases of drug/device development from early stage to commercialization and post-approval support, both in Europe and the US. Through our experience, expertise, and dedication we help (bio)pharma, biotech and medical device companies to stay one-step ahead in the project planning and development of their product portfolios, easing the way towards successful market access.

ProPharma Group employees have experiences from large international to small research companies as well as authorities such as EMA, FDA and national competent authorities.

1.2. Cell and Gene Therapy Experience

ProPharma Group Cell and Gene Therapy specialists support our clients in the development of cell and gene therapies globally. We collaborate with our clients to solve complex challenges and add value to their products.

Our "Cell & Gene Therapy Center of Excellence" offers a platform of services that can boost the development of your product in a time and cost-effective manner. Wherever you are in the development lifecycle, ProPharma Group's experts will effectively progress your development program with the aim to bring your product to patients through a clinical trial or a marketing authorization.

We are a tremendous experienced high-quality team of cell and gene therapy specialists, providing a global and multidisciplinary science-driven consultancy service. In our Cell & Gene Therapy Center of Excellence we provide a team of scientists, engineers, non-clinical, clinical, quality, pharmacovigilance and regulatory experts that integrate their knowledge into your development strategies. We identify gaps, present solutions, liaise with global health agencies and transform hurdles into opportunities.

Our team of specialists support the challenges that develop during the product development life cycle of a cell and gene therapy:

- Proof of principle & safety data to enable clinical studies
- Design of manufacturing process and control strategy
- Formulation optimization

- GxP compliance and the design of pivotal clinical studies along with medical writing
- Maintenance activities including, pharmacovigilance, variations to the marketing approval, etc. that need to be managed

Our team has the technical, scientific, and regulatory experience required to solve the most challenging problems encountered during every step of a product's lifecycle. This knowledge is needed to bring a product to market and ensuring continued success after approval.

2. Executive Summary

IRST is the regional reference center for the treatment and research of oncological diseases in Emilia Romagna, Italy.

The institute hosts two cell factories for the production of experimental ATMP for phase I and II clinical trials.

The first cell factory has been in operation since 2012 and is dedicated to the production of vaccines based on pulsed dendritic cells (somatic cell therapy medicinal product). The second cell factory is being activated and will be dedicated to the production of investigational gene therapy medicinal products (CAR-T cells). The second cell factory will therefore have to be inspected by both the drug regulatory agency (AIFA) and the Ministry of Health for compliance with the regulations for the handling of genetically modified organisms (GMOs).

IRST has approached ProPharma Group for support with safety training related to the handling of GMOs, involving two days training on-site.

GMOs for Gene Therapy Training; Preliminary agenda (to be agreed with IRST)

1. Esecuzione di una valutazione della classe dell'impiego confinato che si intende eseguire (art. 5 del D. L.vo 206/01).
2. Notifica di impianto MOGM
3. Notifica di impiego MOGM
4. Biosicurezza
5. Supply chain di un prodotto di terapia cellulare modificato geneticamente (CAR-T Cells)

The language of the training must be Italian.

3. Statement of Work

3.1. Safety training for the handling of MOGMs

Deliverable	Estimated hours
Safety Training <ul style="list-style-type: none"> - Preparation; 6 hours - Training; 2x days (6 hours each day) 	18 hours

3.1.1. Cost Model

Invoicing will be according to time and material spent:

Resource	Estimated Cost
Senior Consultant/Project Manager	180 EUR/hour

3.1.2. Travel and Related Expenses

Travel costs and related expenses will be charged directly, against copies of receipts. The following travel arrangements or cost will be applicable:

- Travel by car: € 0.62 per km

Travel time of staff will be charged per person:

- For travel inside country of residence: € 90.00 per hour

The estimated time for travel is 2 hours return trip (4 hours).

3.1.3. Confirmation of costs

Deliverable	Costs
Safety Training (preparation and delivery)	
- 18 hours @ €180/hr	€3,240
Travel time & expenses	
- 4 hours @ €90/hr	€360
- Mileage (est. 160km @ €0,62/km)	€100
Total	€3,700

4. Timelines

Work will start upon signature of contract and timelines for delivery will be agreed with IRST.

5. Other

- This proposal is valid until 31-12-2021
- Invoicing will be according to time and material spent.
- Other direct costs such as business trips, application costs, material costs, etc. shall only be invoiced after consultation with IRST.
- Confidentiality Disclosure: This document and its appendices are solely for evaluation purposes of ProPharma Group's services and contains information intended for use by IRST only. It may contain privileged, confidential, and/or trade secret information, and is protected from disclosure under applicable law.
- All costs are in Euro excluding VAT. All volumes are estimates, billing will be made monthly according to time spent
- Our payment term is 30 days after invoice date. Our invoices are always accompanied with a detailed description of the provided services of each invoiced item.