

International Tutorial on Cancer Immunotherapy Research Studies Design (Tideio)

**Intensive Tutored Training to become an International Expert in the Design of Preclinical
and Clinical Studies of Cancer Immunotherapy**

1.Introduction

The different modalities of Cancer Immunotherapy whether cellular, monoclonal antibodies, different vaccine modalities or oncolytic viruses have changed the traditional diagnostic-therapeutic approach in many of our cancer patients.

At the same time, there has been a progressively increasing change in the design of cancer immunotherapy studies, In order to optimize the benefit of our patients in the shortest period of time the preclinical level, in-vitro or animal models, and at the clinical level, to try to benefit our patients in their different phases of development.

The final success of a given research study depends on the appropriate design of methods, objectives and real implementation of the clinical the preclinical study, and whether it can later be replicated or its application generalized to all our patients.

Thus arises the need to bring together the best worldwide experts and trainers in this International Tutorial on Cancer Immunotherapy Research Studies Design

2. Objectives

The main objective of the tutorial is to train professionals from preclinical, clinical or management areas in the design of Cancer Immunotherapy studies to become international experts in this field.

The participants will perform this one-week training in an intensive way, with a personalized tutoring, in order to develop as much as possible their previous skills.

3. Key dates.

Documentation Submission Period: From 15th March to 15th July, 2021

Admission Communication: Before 15th September, 2021

Registration Deadline: Before 1st October, 2021

4. Tutorial Dynamics

4.1 Admission Process

1. **Candidate profile:** graduate in a biosanitary career, professional in the clinical or preclinical area or pharmaindustry professional will be considered as a candidate. A maximum of 36 candidates (6 groups of 6 candidates) will be admitted to the tutorial.
2. **Submission documentation period:** *March 15 to July 15, 2021*. Candidates will send to tideio@hmhospitales.com the following documentation :
 - A draft of a preclinical or clinical cancer immunotherapy proposal for a research study, they will develop during their training stay (online).
 - An updated CV (English).
 - A personal letter of introduction (English).
 - A letter of recommendation from their supervisor or at least two members of the research team (English).
3. **Staff evaluation:** The Director and the TiDeIO expert trainers will evaluate:
 - Draft, research project (1-10 points).
 - CV and letter of recommendation (1-10 points).
4. **Communication of admission:** Researchers will be informed of the result of their admission process *before 15th September, 2021*.
5. **Registration deadline:** Once the candidate is admitted, the registration will be formalize in the following 15 days.

4.2. Intensive on-line Working days

The Tutorial is organized on 6 days of intensive online work, with global Master Lectures, work in small groups and individual tutoring, with a final celebration and awrds ceremony on day 6.

The admitted candidate will receive two weeks before the beginning of the tutorial the drafts of the colleagues of his "small working group" (6 investigators per group).

Working days Structure (days 1 to 5)

7:00 Breakfast (Round of informal presentation of the investigator on day 1, informal conversation on days 2 to 5)

7:45-8:45 Master Lecture: Talk on Advanced Concepts on Cancer Immunotherapy Studies Design by one of the expert trainers The talks will cover:

Global Design, Objectives, Material and Methods, Statistics and Feasibility-Oportunity

In preclinical and clinical studies of Immunotherapy according to the 5 previous categories.

9:00-10:30 Analysis of the drafts in small groups by sections (15' per draft) *.

Day 1: Overall design, introduction, hypothesis and bibliography.

Day 2: Main objective and adequacy of the design to the working hypothesis.

Day 3: Main objective, secondary objectives and statistical analysis.

Day 4: Material and Methods

Day 5: Study Budget - Feasibility/Opportunity.

10:30-12:00 Individualized Analysis of the drafts with one of the trainers.

The corresponding section of the day (1 to 5) previously analyzed by the investigators small groups in the previous sessions

12:00-13:30 Personal work of the investigator on the analyzed section. (*It will be sent to the assigned trainer at 13:30 PM).

13:45 -15:00 Lunch.

15:00-16:30 "Old stories from my research experience": Informal talk given by one of the trainers about occurrences from their research experience that may illustrate certain key points in the research

.16:30 to 17:00 Free time

17:00 to 19:00 "Lessons of the day" Global presentation by the trainers of the most representative or instructive "changes" of the different drafts in the section corresponding to that day (20' talk by each trainer) and suggestions for the following day's section.

19:00 to 20:00 Free time (sports activity, walk, thinking, prayer).

20:00 to 21:00 Personal preparation of the next day's section (*It will be sent to the trainer at 21:00).

Day 6 Structure

7:00 Breakfast (5 ´ Brief intervention by each of the trainers)

7:30-10:30 Final presentation of the Protocols Part 1 (10' per investigator)

10:30-11:00 Break

11:00-14:00 Final Protocol presentation Part 2 (10' per investigator)

14:00 -15:00 Award ceremony.

15:00-15:05 Brief closing remarks by the Tutorial director.

4.3 Environment, language, working conditions

The director and all the expert trainers will care to maintain a jovial work atmosphere. The different indications to the investigator will be made within a great respect to the person and their culture.

As specified, the tutorial will be completely online, so the trainers must stimulate, from the beginning, the active, concrete and effective participation of the investigator, establishing turns of speech, taking care of each one of them individually.

It is essential to respect the investigators' free time and personal work time.

Investigators can make up to three personal questions by e-mail to their trainer about the section of their draft to be analyzed the following day. These e-mails will be answered by the trainer between 21:00 and 23:00 P.M of the same day.

If the question is about statistical issues, the mail will be sent to the predetermined expert statistical advisor for your project, with copy to your trainer. The statistical expert will reply on the same day too.

5. Trainers

5.1 Requirements

The trainers must be active professionals with prestige and publications at national and international level in oncological immunotherapy and with proven knowledge in the dynamics of the design of oncological immunotherapy trials.

There will be 5 tutorial trainers, and two statistical advisors who will act transversally for the investigators and the trainers.

5.2 Trainers and statistical advisors

-Director:

-Dr. Antonio Cubillo (CIOCC)

Trainers:

-Dra. Clara Montagut (Hospital del Mar)

-Dr. Emiliano Calvo (START)

-Dra. Jordi Remon (CIOCC)

-Dra. Valentina Boni (START)

-Dra. Elena Sevillano (CIOCC)

-Dra. Paloma Peinado (CIOCC)

Statistical consultant

-Dr. Borja Fernández

-Dr. Javier Zamora