



## CLINICAL TRANSFER OF EV-BASED THERAPEUTIC PRODUCTS



a GEIVEX workshop on clinical translation of Extracellular Vesicles  
Badalona & Barcelona, Spain & Virtual  
26-27 June 2023

### Organizing Committee:

- Pilar Martin Duque, PhD, *Universidad de Zaragoza, co-chair*
- Marta Monguió-Tortajada, PhD, *Institut d'Investigació Germans Trias i Pujol, Badalona; and University of Lausanne, Switzerland, co-chair*
- Marcel·la Franquesa, PhD, *Institut d'Investigació Germans Trias i Pujol, Badalona*
- Lydia Álvarez-Erviti, PhD, *Center for Biomedical Research of La Rioja*
- María Yáñez-Mó, PhD, *UAM/IIS-IP, CBM, Madrid; GEIVEX president*

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## CLINICAL TRANSFER OF EV-BASED THERAPEUTIC PRODUCTS

### Workshop program

#### DAY 1: 26<sup>th</sup> June 2023 – LECTURES AND DISCUSSION.

Location: Germans Trias i Pujol Research Institute, Badalona & online

**9:30-10h.** Registration

**10-10:20h.** INAUGURATION

#### **10:20-11:30h. SESSION 1: CELL AND GENE THERAPY DEVELOPMENT FOR CLINICAL APPLICATION**

- 1.1. **How to turn a cell production into clinical grade: what does GMP mean and entail?**  
Luciano Rodríguez (Blood and Tissue Bank, Barcelona, Spain) (20 min)
- 1.2. **Manufacturing of cell therapy products and ATMP development.**  
Joaquim Vives (Blood and Tissue Bank, Barcelona, Spain) (20 min)
- 1.3. **Our experience at CliniStem: a gene and cell therapy GMP facility.**  
Begoña Díez Cabezas (CIEMAT, CliniStem cleanroom facility, Madrid, Spain) (20 min)

**11:30-12:00h. SPONSORS TALKS (1/2):** Aplitech Biolab, FiberCell Systems

**12:00-12:30h.** COFFEE BREAK

#### **12:30-13:40h. SESSION 2: REGULATORY AFFAIRS**

- 2.1. **Biological therapy: the experience of the Spanish Regulatory Agency.**  
Pablo de Felipe (AEMPS, Madrid, Spain) (20 min)
- 2.2. **Regulatory affairs on EV therapies: the experience of the Austrian Regulatory Agency.**  
Silke Dorner (Austrian Medicines and Medical Devices Agency (AGES MEA), Vienna, Austria) (20 min)
- 2.3. **The French experience.**  
Sébastien Banzet (EVOLVE group; INSERM, Paris, France) (20 min)

**13:40-14:20h. Q&A on EV therapies and regulatory issues**

**14:20-15:30h.** LUNCH

**15:30-16:00h. SPONSORS TALKS (2/2):** Miltenyi Biotec, Izasa scientific

### 16:00-18:00h. **SESSION 3: ACADEMIA AND INDUSTRY FOCUSED ON EV THERAPIES**

- 3.1. **Academic CART19 manufacturing for anti-tumour immunotherapy.**  
Manel Juan (Hospital Clínic, Barcelona, Spain) (20 min)
- 3.2. **A platform for therapeutic engineered EV.**  
Robert Mamoun (Ciloa, Montpellier, France) (20 min)
- 3.3. **EV vaccines against infectious diseases: *the long and winding road of Innovex Therapeutics S.L.***  
Hernando del Portillo (ISGLOBAL-IGTP, Badalona, Spain) (20 min)
- 3.4. **EV for osteoarthritis.**  
Francisca Alcayaga (IMPACT, Universidad de los Andes, Santiago de Chile, Chile) (20 min)
- 3.5. **The journey towards the industrialization of EVs.**  
Davide Zocco (Lonza, Siena, Italy) (20 min)

### 18:00-18:30h. Q&A on EV therapies translation

## DAY 2: 27<sup>th</sup> June 2023 – CLEANROOM VISIT AND TPP WORKSHOP

Location: Blood and Tissue Bank of Catalonia (BST), Barcelona

9-9:15h. Registration

9:15-10:30h. **Get your Target Product Profile (TPP) and product quality attributes (QTPP) canvas ready**

10:30h Organize workshop participants into two subgroups (1 & 2) to participate in:

**(A) Visit to cleanroom facilities**

Joaquim Vives, Cristina Prat-Vidal (BST)

**(B) Design and improve your TPP and QTPP canvas**

Luciano Rodríguez (BST)

10:40-11:20h 1-A / 2-B

11:20-11:50h COFFEE BREAK

11:50-12:30h 1-B / 2-A

12:30-13:30h **CONCLUSIONS AND FAREWELL**



## CLINICAL TRANSFER OF EV-BASED THERAPEUTIC PRODUCTS

### ABOUT THE WORKSHOP & REGISTRATION

This event focuses on giving a first grasp of the steps needed for clinical translation for EV-based products to members of GEIVEX. Researchers working on EV therapeutics may benefit from attending this workshop sessions including GMP basics and requirements to regulatory issues and the industry viewpoint, given by experts in the field of cell and gene therapy, clinical and regulatory bodies.

The workshop will take place in Badalona & Barcelona, on 26-27 June 2023, at the Germans Trias i Pujol Research Institute (IGTP, Badalona), and the Blood and Tissue Bank (BST, Barcelona).

The workshop will be organized in two different days. In day 1, attendees will have lectures and roundtables separated on three different sections: (1) "Cell and gene therapy development for clinical application", (2) "Regulatory affairs", (3) "Academia & Industry focused on EV therapies". In day 2, we are planning on a fully interactive workshop, including a visit to clean room facilities and a hands-on discussion of their own TPP design.

**This workshop is open only to GEIVEX members. If you are interested to attend and not yet a GEIVEX member, you only need to register [here](#).**

We offer **three modalities** for this workshop:

- 1.- Online** attendance to Day 1 lectures. A 25€ fee applies.
- 2.- Presential** attendance to **Day 1** lectures only. A 50€ fee applies.
- 3.- Presential** attendance to **both Day 1 & Day 2**. A 50€ fee applies. Given the limitations of attendees to the presential activities planned for the 2nd day, selection for day 2 attendance will be performed based on the answers given in the questionnaire. Selection will be communicated timely to registrants.

#### How to formalize the registration:

1. Fill in the questionnaire: [link](#)
2. Pay the corresponding fee according to the modality of attendance to GEIVEX:  
IBAN: ES32 2100 2614 7013 0053
3. Send the proof of payment to: [secretaria@geivex.org](mailto:secretaria@geivex.org) indicating "Clinical workshop", your name and the modality you chose: online/onsite

*Registration form questionnaire:*



## Travel & accommodation

### DAY 1: 26<sup>th</sup> June 2023 – LECTURES AND DISCUSSION.

**VENUE:** Germans Trias i Pujol Research Institute (IGTP)

Ctra de Can Ruti, Camí de les Escoles s/n | 08916 Badalona (Barcelona), Spain

[How to get there](#) | [maps](#)

### DAY 2: 27<sup>th</sup> June 2023 – CLEANROOM VISIT AND TPP WORKSHOP

**VENUE:** Blood and Tissue Bank of Catalonia (Banc de Sang i Teixits, BST)

Edifici Dr. Frederic Duran i Jordà | Passeig Taulat, 116 | 08005 Barcelona, Spain

[How to get there](#) | [maps](#)

## HOTELS

### Hotel Miramar Badalona\*\*\*

*With special rates for workshop participants, see details below. 30min by bus to IGTP. A shuttle bus to IGTP/BST will be provided from its vicinity.*

C/ de Santa Madrona, 60 | 08911 Badalona (Barcelona) | [maps](#)

(+34) 933 840 311 | [www.hotelmiramar.es](http://www.hotelmiramar.es) | [reservas@hotelmiramar.es](mailto:reservas@hotelmiramar.es)

Tarifas para las fechas del 26 y 27 de junio 2023:

- Habitación básica doble de uso individual sin vistas al mar 75,00€/noche
- Habitación básica doble de uso individual con vistas al mar 90,00€/noche
- Habitación doble de uso individual sin vistas al mar 104,50€
- Habitación doble de uso individual con vistas al mar 116.60
- Habitación con terraza y vistas al mar 141,90€
- Tasa turística no incluida 0,66€/persona/día

Garantía:

- Pago del importe equivalente a la primera noche en el momento de efectuar la reserva.
- Resto del pago se podrá hacer en el hotel.

Política de cancelación:

- Cancelación sin gastos si la reserva se cancela antes del 15/06/2023.
- Cancelada en fecha posterior al 15/06/2023, el importe cobrado como garantía será considerado como gastos de cancelación.

Habrà que hacer referencia al congreso “**GEIVEX**” en el momento de realizar la reserva, por teléfono (+34 933 840 311) o a través del mail [reservas@hotelmiramar.es](mailto:reservas@hotelmiramar.es).

### **Rafaelhoteles Badalona\*\*\*\***

*5 min walk from M28 bus going to IGTP (22min total)*

Av. de Navarra, 6-8 | 08911 Badalona (Barcelona) | [maps](#)

(+34) 931 847 900 | [hotel webpage](#) | [badalona@rafaelhoteles.com](mailto:badalona@rafaelhoteles.com)

### **Hostal Solimar\*\***

*3 min walk from shuttle bus to IGTP*

C/ de la Caritat, 29 | 08911 Badalona (Barcelona) | [maps](#)

(+34) 933 895 003 | [www.hostalsolimar.com](http://www.hostalsolimar.com) | [info@hostalsolimar.com](mailto:info@hostalsolimar.com)

### **Hostal Badaloni\*\***

*3 min walk from M26 and M28 buses going to IGTP (38min total)*

C/ Baldomer Solà, 57 | 08912 Badalona (Barcelona) | [maps](#)

(+34) 933 888 899 | [www.hostalbadaloni.com](http://www.hostalbadaloni.com) | [info@hostalbadaloni.com](mailto:info@hostalbadaloni.com)

### **Be Dream Hostel Barcelona\*\***

*3 min walk from M26 and M28 buses going to IGTP (38min total)*

Av. Alfons XIII, 28B | 08912 Badalona (Barcelona) | [maps](#)

(+34) 933 991 420 | [www.behostels.com/dream](http://www.behostels.com/dream) | [dream@behostels.com](mailto:dream@behostels.com)

**WE LOOK FORWARD TO WELCOMING YOU SOON!**

If you need any clarification on the Workshop program, please get in touch with:

[secretaria@geivex.org](mailto:secretaria@geivex.org) ; [mpmartind@gmail.com](mailto:mpmartind@gmail.com); [mmonguio@igtp.cat](mailto:mmonguio@igtp.cat)