



INTERNATIONAL SOCIETY *for*
EXTRACELLULAR VESICLES

EV-based biomarkers: Commercialisation and clinical implementation

Program



Aalborg, Denmark
12th-14th October 2023

INTRODUCTION

The ISEV Extracellular Vesicle (EV)-based biomarkers workshop aims to discuss key challenges in commercialisation and clinical implementation of EV-based biomarkers. The biomarker potential of EV, and their application as liquid biopsies, was first demonstrated over two decade ago. Whilst considerable contemporary interest exist in using EVs as biomarkers for a wide range of diseases, progress in the field is hindered by a lack of development of EV-based biomarkers under formal regulatory requirements.

THIS FIRST ISEV WORKSHOP TO ADDRESS THESE TOPICS WILL COMPRISE A SMALL GROUP OF ABOUT 50 EXPERTS TO DISCUSS IN SHORT TALKS AND ROUNDTABLE MEETINGS THE FIVE MAIN TOPICS:

- Topic 1: Clinical need, commercial viability, and feasibility for EV biomarkers
- Topic 2: Discovery of candidate EV biomarker(s)
- Topic 3: Biomarker verification and scientific validation
- Topic 4: EV biomarker prototype development and testing
- Topic 5: EV biomarker implementation, regulatory considerations, and business models

The workshop will be held in Aalborg (Denmark) from 12th to 14th October 2023. The Workshop will be in-person only.

<https://www.isev.org/ev-based-biomarkers>

International Organizing Committee

Carlos Salomon (co-chair) – The University of Queensland (Australia)

Aase Handberg (co-chair) – Aalborg University (Denmark)

Metka Lenassi - University in Ljubljana, Slovenia

Andreas Möller - The Chinese University of Hong Kong

Saumya Das – Harvard University (USA)

Malene M Jørgensen - Aalborg University (Denmark)

Raghu Kalluri - MD Anderson Cancer Center (USA)

Lorraine O'Driscoll - Trinity College Dublin



13:00 – 13:15 Workshop Opening and Introduction of Outcome Aims, Remarks on ISEV Workshops *Carlos Salomon / Aase Handberg / Metka Lenassi*

Topic 1: Clinical need, commercial viability, and feasibility for EV biomarkers

13:15 – 13:35 Introductory Talk
Chair: Aase Handberg

Speaker: Valerie Daussin – The Biomarker Commercialization (BIC) Guide

Short talks from Abstracts (Topic 1)
Chair: Saumya Das

- 13:40 – 13:50** Konstantin Glebov - Bridging the Gap: Translating Exosome-Based Biomarker Discoveries from University Laboratories to Industrial Applications
13:50 – 14:00 Soumyalekshmi Nair - GDM-PROMISE: Gestational Diabetes Mellitus - Pioneering Detection Method to Promote Maternal and Infant Health
14:00 – 14:10 Francesca Torrini - Programmable affinity-based coacervates for urinary extracellular vesicles analysis

14:10 – 14:20 Sponsor Talk 1: IZON, Stephane Mazlan *Setting the Foundation: Refining EV Isolation Workflows for EV Biomarker Progress*

10 min Q&A

14:30 – 15:30 Coffee Break

15:30 – 15:50 Introductory Talk
Chair: Carlos Salomon

Speaker: Raghu Kalluri - MD Anderson Cancer Center (USA)

15:55 – 16:05 Sponsor Talk 2 - TBA

10 min Q&A

16:15 – 17:30 Roundtable Discussions (2 Breakout Rooms) - Introduction to discussions – Each room one topic

- Topics session 1**
Group 1: Clinical Need, Commercial Viability
Chairs: Saumya Das, Jonathan Degosserie, Michelle Gomes, Vivek Tanavde
Group 2: Feasibility and Discovery
Chairs: Raghu Kalluri, Kristiina Kurg, Jessica Gobbo, Cristina Catoni

17:30 – 18:30 Reporting from Breakout Rooms and General Discussion
Chairs: Andreas Möller and Jennifer Jones

19:00 Dinner

Venue - Innovate, Aalborg University, Thomas Manns Vej 25, 9220 Aalborg, DK



8:45 – 9:00 Welcome and Introduction for the Day *Carlos Salomon / Aase Handberg*

Topic 2: Discovery of candidate EV biomarker(s)

9:00 – 9:20 Introductory Talk

Chairs: Lorraine O'Driscoll and Quentin Lubart

Speaker: Andreas Möller (focus on discovery)

Short talks from Abstracts (Topic 2)

Chairs: Lorraine O'Driscoll and Quentin Lubart

9:25 – 9:35 Christa Noehammer - EV-based biomarkers for complex disease diagnostics from blood, saliva or cerebrospinal fluid

9:35 – 9:45 Tomas Miguel De Freitas Dias - Targeted isolation of hepatocyte-derived EVs from human plasma and discovery of novel miRNAs and protein biomarkers in hepatocellular carcinoma

9:45 – 9:55 Sponsor Talk 3

25 min Q&A

10:20 – 11:00 Coffee Break

Topic 3: Biomarker verification and scientific validation

11:00 – 11:20 Introductory Talk

Chairs: Malene Møller Jørgensen and Elena Martens-Uzunova

Speaker: Takahiro Ochiya - Extracellular vesicles as a promising biomarker resource in liquid biopsy for cancer

11:25 – 11:35 Sponsor Talk 4

Short talks from Abstracts (Topic 3)

Chairs: Malene Møller Jørgensen and Elena Martens-Uzunova

11:35 – 11:45 Kathyn Neville - The μ SiM-EV– A Platform for Rapid and Simplified Detection of Single Extracellular Vesicle Molecular Cargo

11:45 – 11:55 Mi Ho Jeong - Verifying the cell-specific extracellular vesicle markers for idiopathic pulmonary fibrosis diagnosis

11:55 – 12:05 Erez Eitan - Analytical validation of Extracellular vesicles immunoaffinity isolation

10 min Q&A

12:15 – 13:30 Lunch

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9220 Aalborg, DK

13:30 – 14:45 Roundtable Discussions (2 Breakout Rooms) - Introduction to discussions – Each room one topic

Topics 2 and 3

Group 1: Discovery of Candidate EV Biomarker(s) – Systematic approach or from clinical need

Chairs: Saumya Das, Alicia Llorente, Simon Powis

Group 2: Biomarker Verification and Scientific Validation

Chairs: Carlos Salomon, Paulo Pereira, Ryan Pink

14:45 – 15:45 Reporting from Breakout Rooms and General Discussion

Chairs: Raghu Kalluri and Nicole Kruh-Garcia

15:45 – 16:30 Coffee Break

Topic 4: EV biomarker prototype development and testing

16:30 – 16:50 Introductory Talk

Chairs: Metka Lenassi and Vytautas Žėkas

Speaker: Klaus Pantel –European Liquid Biopsy Society (ELBS)

16:55 – 17:05 EV working group – ELBS – Rienk Nieuweland

Short talks from Abstracts (Topic 4)

Chairs: Metka Lenassi and Vytautas Žėkas

17:05 – 17:15 Monica Suet Ying - Clinico-laboratory infrastructure for EV biomarker discovery and testing

17:15 – 17:25 Dario Brambilla - Automated in-line separation and detection of extracellular vesicles for biomarker validation

10 min Q&A

17:35 - 18:30 Roundtable Discussions (2 Breakout Rooms) - Introduction to discussions – Each room one topic

Topic 4

Group 1: Prototype development – how and who

Chairs: Andreas Möller, Takahiro Ochiya, Olivier Loudig, Shruti Jain

Group 2: Prototype testing – who and where

Chairs: Aase Handberg, Anthony Couvillon, Rami Alsati, Khirul Islam

18:30 – 19:00 Reporting from Breakout Rooms and General Discussion

Chairs: Andreas Möller and Aase Handberg

19:00 Dinner (On Own) *We could book a restaurant for everyone, but at their own costs.*

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Day 3 Saturday 14th October

8:45 – 9:00 Welcome and Introduction for the Day *Carlos Salomon / Aase Handberg*

Topic 5: EV biomarker implementation, regulatory considerations, and business models

9:00 – 9:20 Introductory Talk

Chair: Carlos Salomon and Giorgia Melli

Speaker: Konstantin Denessiouk, R&D Manager, CEO of Labmaster

9:25 – 9:35 Sponsor Talk 5

Short talks from Abstracts

Chairs: Carlos Salomon and Giorgia Melli

9:35 – 09:45 Natasa Zarovni Stoichiometric constrains for detection of EV born biomarkers and their impact on technological and economic viability of EV diagnostics (a banana peel or appeal?)

9:45 – 9:55 Elina Aleksejeva Multiomic signature of EVs provides a non-invasive way to assess the readiness of endometrium for embryo implantation

9:55 – 10:15 Introductory Talk

Chairs: Carlos Salomon and Giorgia Melli

Speaker: Saumya Das – EV Biomarkers from a clinical perspective

10:20 – 10:30 Sponsor Talk 6

10 min Q&A

10:40 – 11:00 Coffee Break

11:00 – 12:15 Roundtable Discussions (2 Breakout Rooms) - Introduction to discussions – Each room one topic

Topics 5:

Group 1: EV Biomarker Implementation – clinical need, national guidelines or how to reach clinical use *Chairs: Saumya Das, Aase Handberg, Maiken Møllergaard, Elena Khomyakova*

Group 2: Regulatory Considerations, and Business Models

Chairs: Carlos Salomon, Raghu Kalluri, Melanie Tepus Petrsoric

12:15 – 12:45 Reporting from 2 Breakout Rooms and General Discussion

Chairs: Carlos Salomon and Saumya Das

12:45 – 13:30 Closing Remarks, Future Plans, Outlook - Are We Ready for the Future? Panel Discussion IOC

13:30 Close Workshop and Lunch to go

Chairs: Carlos Salomon / Aase Handberg

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