

# Update from WG4

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# WG4 update

The WG#4 has three main objectives:

- 1) the preparation of guidelines and organization of eventual early clinical trials in oncology of the selected nanotechnology
- 2) tackled challenges in nanomedicines regulatory and translational science such as issues related to dose scaling, PK/PD relationship and personalized medicine
- 3) standardization of clinical trial guidelines for nanoformulations and nanomedicine-based pharmaceuticals in oncology with a direct interaction with European Medicines Agency

Our Deliverables for the end of our Action (M48):

- D4.1. Formulation of guidelines and documents for translation of nanomedicines from bench to bed/market
- D4.2. Formulation of guidelines and documents concerning regulatory aspects of nanomedicines
- MS4.1. Documents for translation of selected nanomedicines
- MS4.2. Documents for suggested regulatory aspects of selected nanomedicines

**54 Members**  
**13 Industry/SMEs**

# WG4 update



## 2021

- 9/2021. Two virtual workshops **MEET OUR INDUSTRIAL PARTNERS** (100 registrations/50- 36 assistants)
- 11/2021. Webinar "**FDA Guidance: Drug Products Containing Nanomaterial**" by Dr. Anil Patri. (98 registrations/50 assistants)

## 2022

- **WG4 INFORMATION DAY.** Online meeting Tuesday 8/2 from 11-12 am CET
- Third Online workshop **MEET OUR INDUSTRIAL PARTNERS** during March. Open call for presenters
- A second Webinar on FDA Guidance and/or Pharmacology will be organized during April-May
- A core team will be established to start to work on the Deliverables of our Group during April. Wrap-up of final documents during the WG4 meeting in 15-16 June in Istanbul

