

Nano2Clinic – Synergies for Clinical Translation of Nanotechnology in Cancer Therapies Zagreb, Croatia, 3 March 2023

The scientific conference Nano2Clinic – Synergies for Clinical Translation of Nanotechnology in Cancer Therapies was held on March 3 in the Great Hall of Školska knjiga in Zagreb. The event was organized under Nano2Clinic: Cost Action CA17140 – Cancer nanomedicine – from the bench to the bedside. With the support of “Pharmaceutical Open Innovation Test Bed for Enabling Nanopharmaceutical Innovative Products” – PHOENIX (funded by European Union Horizon 2020 Programme under grant agreement n° 953110) and “Safe-by-Design Approach for Development of Nano-Enabled Delivery Systems to Target the Brain” – SENDER (funded by the European Social Fund). The local organizer of the meeting was the Institute for Medical Research and Occupational Health in Zagreb under the leadership of Ivana Vinković Vrček, while additional support was provided by seven sponsors (Biovit, AlphaChrom, Croatian Tourist Board, City of Zagreb, Yassenka, Medic, Gorea Plus). The scientific program of the lectures focused mainly on three factors discussed by the participants: safety aspects, regulatory aspects and aspects of training and education for a well-qualified workforce and patients. The event was attended by 47 participants from as many as 15 countries. The meeting was officially opened by the main organizer Ivana Vinković Vrček, after which the deputy director Irena Brčić Karačonji gave a few words on behalf of the Institute for Medical Research and Occupational Health. Afterwards, Ivica Malnar from HALMED, the Agency for Medicinal Products and Medical Devices, gave an introductory lecture on the Croatian market and regulations. After the introductory greetings and lectures, presentations on the goals and successes of the Nano2Clinic and Phoenix projects followed by the lecturers: Sabrina Pricl, University of Trieste, CA17140 Chair; *Cost Action CA17140 Nano2Clinic achievements* and lecturers: Nazende Günday-Türelı, MyBiotech GmbH, PHOENIX-OITB Coordinator; *PHOENIX-OITB project presentation*. Then, in the second part, the topic of discussion was best practice, where presentations were given by lecturers: Elisabet Gonzales, Institut de Ciència de Materials

de Barcelona (CSIC)-CIBER-BBN; *Best practice: Clinical translation of orphan nanodrug*, and lecturer: Marija Plodinec, CEO ARTIDIS; *Best practice: Nanotool for cancer diagnostics*. In the third section of the meeting, there were three presentations on the importance of regulations by the lecturers: Jon de Vlieger, Strategy Director at Foundation Ligateure; *International regulatory advances for Nanomedicines and their follow-ons*, lecturer: Mike Isles, Executive Director, The European Alliance for Access to Safe Medicines; *The importance of having the right policies and regulations in place to ensure patient safety – the case for nanomedicines*, lecturer: Marco Giardiello, University of Liverpool, British Society for Nanomedicine; *Novel Approaches to Theranostic Nanomedicine Design*. Lastly, the final three presentations on risk assessments of nanomedicines were held by the lecturers: Ulf Kahlert, Otto-von-Guericke-Universität Magdeburg, Faculty of Medicine; *Target efficacy vs. Off-target risk of nanodrugs: Lessons learned from individualization of chemotherapies using co-clinical organoid test system*, lecturer: Blanca Suarez Merino, Regulatory Affairs Director, Nanotechnology Industries Association NIA; *Regulatory aspects of clinical translation of nano-enabled products*, lecturer: Maria Dusinska, RiskGone Project Coordinator, Norwegian Institute for Air Research – NILU; *Risk Assessment in Nanomedicine*. The presentations were followed with great attention by the participants, and each lecture was followed by a rich discussion. The ceremonial closing of the meeting was enriched by the Ethno Club Zagreb, where the dancers through song and dance, presented Croatian cultural heritage, thus brightening everyone’s mood. This meeting aimed to strengthen relationships between industry, the R&D&I sector, regulatory agencies, clinics, and patients with the ultimate goal of fostering the clinical transfer of nanomedicine from table to bedside. By promoting scientific exchange, technological implementation, and innovative solutions, the meeting enabled a dialogue to rationalize and focus EU-level research efforts in the face of the great challenge of translating nanomedicine for cancer therapies.

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Zagreb, Hrvatska, 3. ožujka 2023.**

Znanstveni skup *Nano2Clinic – Synergies for Clinical Translation of Nanotechnology in Cancer Therapies* održan je 3. ožujka u Velikoj dvorani Školske knjige u Zagrebu. Događaj je organiziran pod okriljem *Nano2Clinic: Cost Action CA17140 – Cancer nanomedicine – from the bench to the bedside*. Uz podršku *Pharmaceutical Open Innovation Test Bed for Enabling Nano-pharmaceutical Innovative Products – PHOENIX* (financirano od programa Europske Unije Horizon 2020 na temelju sporazuma br. 953110) i *Safe-by-Design Approach for Development of Nano-Enabled Delivery Systems to Target the Brain – SENDER* (financirano od Europskog Socijalnog Fonda). Lokalni organizator skupa je bio Institut za medicinska istraživanja i medicinu rada u Zagrebu pod vodstvom Ivane Vinković Vrček, dok je dodatnu potporu pružilo sedam sponzora (Biovit, AlphaChrom, Hrvatska turistička zajednica, Grad Zagreb, Yasenka, Medic, Gorea Plus). Znanstveni program predavanja je bio usredotočen na tri čimbenika o kojima su sudionici raspravljali: sigurnosni aspekti, regulatorni aspekti te aspekti osposobljavanja i obrazovanja za dobro kvalificiranu radnu snagu i pacijente. Događaju je prisustvovalo 47 sudionika iz čak 15 zemalja. Skup je službeno otvorila glavna organizatorica Ivana Vinković Vrček, nakon čega je zamjenica ravnateljice Irena Brčić Karačonji u ime Instituta za medicinska istraživanja i medicinu rada uputila pozdravnu riječ. Na kraju je uvodno predavanje o hrvatskom tržištu i regulativama održao Ivica Malnar iz HALMED-a, Agencije za lijekove i medicinske proizvode. Nakon uvodnih pozdrava i predavanja uslijedile su prezentacije o ciljevima i uspjesima Nano2Clinic i Phoenix projekata od predavačice: Sabrina Pricl, University of Trieste, CA17140 Chair; *Cost Action CA17140 Nano2Clinic achievements* i predavačice: Nazende Günday-Türeli, MyBiotech GmbH, PHOENIX-OITB Coordinator; *PHOENIX-OITB project presentation*. Zatim, u drugom dijelu je bilo govora o najboljoj praksi, gdje su izlaganja održale predavačice: Elisabet Gonzales, Institut de Ciència de Materials de Barcelona (CSIC)-CIBER-BBN; *Best practice: Clinical translation of orphan nanodrug*, i predavačica: Marija Plodinec, CEO ARTIDIS; *Best practice:*

Nanotool for cancer diagnostics. U trećoj sekciji skupa uslijedila su tri predavanja o važnosti regulacija od predavača: Jon de Vlieger, Strategy Director at Foundation Lygature; *International regulatory advances for Nanomedicines and their follow-ons*, predavač: Mike Isles, Executive Director, The European Alliance for Access to Safe Medicines; *The importance of having the right policies and regulations in place to ensure patient safety – the case for nanomedicines*, predavač: Marco Giardiello, University of Liverpool, British Society for Nanomedicine; *Novel Approaches to Theranostic Nanomedicine Design*. Na kraju su održana posljednja tri predavanja o procjenama rizika kod nanolijekova od predavača: Ulf Kahlert, Otto-von-Guericke-Universität Magdeburg, Faculty of Medicine; *Target efficacy vs. Off-target risk of nanodrugs: Lessons learned from individualization of chemotherapies using co-clinical organoid test system*, predavačica: Blanca Suarez Merino, Regulatory Affairs Director, Nanotechnology Industries Association NIA; *Regulatory aspects of clinical translation of nano-enabled products*, predavačica: Maria Dusinska, RiskGone Project Coordinator, Norwegian Institute for Air Research – NILU; *Risk Assessment in Nanomedicine*. Izlaganja su bila praćena s velikom pažnjom sudionika te je nakon svakog predavanja uslijedila zanimljiva rasprava. Svečano zatvaranje skupa obogatio je Etno Klub Zagreb u sklopu kojeg su plesači i plesačice kroz pjesmu i ples prezentirali hrvatsku kulturnu baštinu, i tako uljepšali atmosferu. Ovaj stručni skup imao je za cilj ojačati odnose između industrije, R&D&I sektora, regulatornih agencija, klinika i pacijenata s krajnjim ciljem poticanja kliničkog prijenosa nanomedicine od stola do kreveta. Promicanjem znanstvene razmjene, tehnološke implementacije i inovativnih rješenja, skup je omogućio dijalog za racionalizaciju i fokusiranje istraživačkih napora na razini EU-a u suočavanju s velikim izazovom translacije nanomedicine za terapije raka.

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