



Deliverable 9

Report on One Health nanotechnology system for animal models studies (M36)

Challenge of reference:

Challenge 3. Not enough control and informed procedures are available to link the environmental impact to drug production and use. Specific guidelines do not exist to address the problem during the whole process from conception to manufacturing and use. *Concepts and strategic support in a guideline/white paper format should be given to the stakeholder in the field for a standard approach to develop safer drugs for humans and animals.*

Objective of reference (Research Coordination Objective)

Objective 3. Coordination of the translation from in vitro-to-in vivo activities to obtain high quality leads and candidates.

Actions: Introduction of omics technologies (genomic, proteomics and transcriptomics) and imaging for a limited number of validated leads. Drug delivery of biodegradable nanotechnology and drug targeting tools applications for both H&A R&D, pharmacology (pharmacokinetics and pharmacodynamics) on animal models by changing drug regimen and study of the effects of the different drug bioavailability tools. This can be acquired through European RTD organization and allow the achievement of high-quality leads with associated biological properties tailored for the H&A VB parasitic infections drug research program. KPI: 3 metrics adopted to measure objective 3 to be reviewed once a year. 3.1 Number of successful examples of biodegradable nanotechnology formulation on dose regimen for each infection. 3.2 Number of projects developed in collaboration with the RTD platform and other stakeholders. 3.3 Number of animal studies including the degradable formulation and targeting vectorization

Working group of reference:

WG3. Coordination of in vitro-to-in vivo translation of One Health leads and candidates. (Challenge 3)

Objectives. Promoting and strengthening of innovative technologies required in the translation of leads and candidates from animal to humans and vice versa to ensure the progression of qualified leads and candidates to the end of the pre-clinical phase and de-risk studies in clinical phase 1. This is restricted to advanced leads and candidate.

T3.1 *One Health nanotechnology system for animal models studies: evaluation of the effect of the delivery approaches with biodegradable systems on the in vivo pharmacokinetics using different animal models (mice, hamsters and dogs). (D3.1)*

Deliverable description (about 100 words)



Nanoparticles are widely used as drug delivery systems due to their adaptability, tailored-made properties and ability to enhance the therapeutic performance of the encapsulated drugs. However, limitations such as cytotoxicity, development of resistance and toxicological risks posed to One Health ecosystems should be considered during the nanoparticles' development. Long-term safety data of nanoparticles are often lacking, raising concerns about bioaccumulation and unintended ecological impacts following environmental release. In addition, cost-effectiveness and integration into existing healthcare systems remain significant hurdles, especially in low-resource settings where vector-borne diseases are mostly prevalent. Addressing these limitations through rigorous toxicological studies, standardization of nanoparticle synthesis, and multidisciplinary regulatory efforts will be essential for realizing the full potential of nanotechnology in the context of new therapeutic agents against VBDs.

Description of what we have done:

Infrastructure

Acquisition within the action network of a technological platform for highly standardized production of nanoformulations and collaborative discovery activities within the network.

Workshops

“Nanotechnology in Global Health: The 2026 Paradigm Shift.” The One Health drugs COST Action and the HIP-Tech PhD School (University of Modena and Reggio Emilia) convene in June 2026 for two international days focused on Nanotechnology in global health. In presence meeting. In June 2026, the One Health drugs COST Action and the HIP-Tech PhD School at the University of Modena and Reggio Emilia convened an international symposium on nanotechnology in global health. The event highlighted how nanotechnology is revolutionizing treatments for Neglected Tropical Diseases through targeted polymeric nanocapsules and enhanced bioavailability via nano-suspensions. Guided by strict regulatory Quality by Design (QbD) standards and a One Health framework, the sector has embraced biodegradable materials, eco-friendly "Green Synthesis" using plant extracts and fungi, and eco-pharmacovigilance to protect ecosystems. Furthermore, machine learning is driving these breakthroughs by optimizing nanocarrier formulas and significantly reducing the need for animal testing across human and veterinary applications. <https://www.onehealthdrugs.com/events/scientific-meeting/meeting-2026/nanotechnologies-applications-and-regulatory-aspects-in-different-therapeutic-area-with-focus-on-infectious-diseases-and-antiparasitic-drugs-leveraging-low-environmental-impact-and-one-health-consideration/>

“Formulation technologies for human and veterinary VBDs to reduce dose and environmental impact” Online event, 13 September 2024 - 14:00-17:00. The workshop presented new formulation technologies for antiparasitic drugs integrating greener principles in line with the One Health approach. <https://www.onehealthdrugs.com/events/scientific-meeting/meeting-2026/nanotechnologies-applications-and-regulatory-aspects-in-different-therapeutic-area-with-focus-on-infectious-diseases-and-antiparasitic-drugs-leveraging-low-environmental-impact-and-one-health-consideration/>

“Green chemistry approaches and innovative drug delivery systems towards reducing environmental impact in antiparasitic drug discovery” Online event, 15th March 2024 14:00-17:00. The workshop explored sustainable practices that reduce the environmental impact focusing on green chemistry and innovative drug delivery systems and their application in antiparasitic drug discovery. During the discussion the concept of developing predictive models able to describe the overall environmental risks to be used to facilitate regulatory decision making clearly emerged. <https://www.onehealthdrugs.com/events/scientific-meeting/past-meetings-in-2024/green-chemistry-approaches-and-innovative-drug-delivery-systems-towards-reducing-environmental-impact-in-antiparasitic-drug-discovery/>



“Strategies for breaking the chain between the parasite reservoir in animals and infections in humans” In-person event, 4-6 June 2025, Antwerp. The conference included the presence of stakeholders who presented their technologies at a technology booth. <https://www.onehealthdrugs.com/events/scientific-meeting/next-meeting/ohd-2025-annual-conference-strategies-for-breaking-the-chain-between-the-parasite-reservoir-in-animals-and-infections-in-humans/>

STSM

Blood brain barrier – derived peptide shuttles for drug delivery to the CNS. Paula Schwarz – Period 13/01/2025 24/01/2025 – (Medical University of Vienna (Vienna, Austria) Vienna – Austria to Uppsala Universitet, Department of Pharmacy, Translational PKPD) - <https://www.onehealthdrugs.com/stsm/stsm-blood-brain-barrier-derived-peptide-shuttles-for-drug-delivery-to-the-cns-paula-schwarz-start-date-13-01-2025-end-date-24-01-2025/>

Interested stakeholders

Experts in medicinal chemistry, nanotechnology, parasitology, pharmacology and environmental toxicology who focus on drug discovery. Organizations seeking innovative antiparasitic compounds and formulations for drug development pipelines. Veterinary and pharma industry and human and animal health professionals. Stakeholders in pharmaceutical R&D emphasizing environmentally sustainable practices. Agencies interested in setting standards and policies for sustainable drug development with low environmental impact. Researchers participating in “OneHealthdrugs” initiatives or similar global programs aiming at interdisciplinary solutions for health challenges.

Scientific impact (from the MoU)

- the discovery and optimization of high number of antiparasitic hits and lead compounds for H&A use with expected environmental low impact and higher quality profile than before;
- the development of biodegradable drug formulations with engineered targeting and engineered conjugates ensuring better *in vivo* animal efficacy.

The long-term benefits (from the MoU)

- substantial improvements of the biological profile in treating parasitic diseases caused by VB parasitic diseases affecting H&A;
- engagement of RTD platforms active in the field;

Innovation

Cross-sectorial and interdisciplinary networking approach to advance the drug discovery and development field in VB parasitic diseases in H&A. Integration of the innovative approaches with the environmental impact concepts, will involve also pharmaceuticals drug discovery, manufacturing and use. New delivery systems employing biodegradable components will enable the development of more efficacious and safer drugs with reduced environmental concerns.