MISSIONE 4
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Innovation, digitalisation and sustainability for the diffused economy in Central Italy

Università degli Studi di Urbino
4 novembre 2022

Kick-off meeting "SPOKE 8"

Presentazione WP 2

Innovative biologics for the treatment of unmet medical needs in rare metabolic disorders and oncology

● Task 2.1 Facility implementation for process development and the production of pre-clinical lots of biologics in class D; ● Task 2.2 Quality control laboratory for biologics; ● Task 2.3 Animal facility of selected mouse models for in vivo efficacy studies.

Milestones	M2.1a Facility design and utilities defined (Y1)	M2.1b Facility equipment selected and tender completed (Y1)	M2.1c Facility open and active (Y2)	M2.2a Representative Product candidates and products libraries defined (Y1)
	M2.2b Production of the selected recombinant enzymes (Y2)	M2.2c In vitro testing of the enzyme in proper cell models (Y2)		M2.2d In vivo testing of the recombinant enzyme in proper animal models (Y3)
	M2.3a Single cell sorting and selection against target antigens - cloning of variable regions gene and library construction for Ab selection (Y1)	M2.3b scFv and full length IgG1 and IgG4 fragments produced and expressed by transient transfection in CHO or ECT cells (Y2)		M2.3c Representative products tested in vivo in proper animal models (Y3)
Outputs	D2.1 New facility for the design, production, characterization and validation of biologics set up (Y3)	D2.1 Fully integrate design for the genetic engineering of newly recombinant enzymes (Y3)		D2.3 Approach for the generation of human Ab validated (Y3)

	TASK 2.1		TASK 2.2		TASK 2.3
Name	Facility implementation for process development and the production of pre-clinical lots of biologics in class D.	Name	Quality control laboratory for biologics	Name	Animal facility of selected mouse models for in vivo efficacy studies
Description	Implementation of a new facility for the production and characterization of biologics to be used in preclinical investigations. Setup of an externally accessible, confidentialitycompliant, infrastructure for the production of synthetic biologics including recombinant enzymes, antibodies and modmRNA in bacteria, yeast and mammalian cells or by synthetic methods.	Description	All validate methods and procedures for the qualification of biologics (including chemical, physical and biological properties) including tests for purity, impurities, endotoxin, residual host cell proteins, residual host cell DNA, potency of products. Qualification of raw materials. Bioburden and absence of viral agents.	Description	The University animal facility will be expanded for the in vivo testing of products generated under WP 1- 3 in proper animal models. The facility has already access to different animal models of human metabolic diseases that will be expanded to additional models in the area of oncology

	TASK 2.1		TASK 2.2		TASK 2.3
	MILESTONE		MILESTONE		MILESTONE
	2.1a Facility design and utilities defined		2.2a Representative Product candidates selected by bioinformatic tools and products libraries defined		2.3a Single cell sorting and selection against target antigens; cloning of variable regions gene and library construction for Ab selection
	2.1b Facility equipment selected and tender completed		2.2b Production of the selected recombinant enzymes in al least two expression systems, at lab scale, purified and in vitro characterization		2.3b scFv and full length IgG1 and IgG4 fragments produced and expressed by transient transfection in CHO or ECT cells
	2.1c Facility open and active		2.2c In vitro testing of the renzime in proper cell models		2.3c Representative products tested in vivo in proper animal models (at least 1 Ab)
			2.2d In vivo testing of the recombinant enzyme in proper animal models		
	Docenti coinvolti		Docenti coinvolti		Docenti coinvolti
	1 Crinelli Rita (PA)		4 Cantoni Orazio (PO)		10 Bianchi Marzia (PA)
	2 Macedi Eleonora (RTDb)		5 Cappiello Achille (PO)		11 Mannello Ferdinando (PO)
	3 Magnani Mauro (PO)		6 Fanelli Mirco (PO)		
			7 Ferretti Stefano (PA)		
			8 Pompa Andrea (PA)		

KPIs

Each Spoke will define qualitative and quantitative Key Performance Indicators (KPIs) to measure progress and achievements. The main principle followed in defining these KPIs is that of clarity, simplicity, measurability, and effectiveness.

Preliminary KPIs set

- Number of new technologies, tools, techniques, products and services developed by the spoke
- Number of companies involved in spoke activities
- Percentage of SMEs on the total number of companies involved in spoke activities
- Number of companies adopting and implementing new technologies and developed products
- Number of human resources from industry and research institutions trained on-the-job
- Number of highly qualified human resources, researchers and PhD students attracted
- Percentage of scholars and researchers from EU and non-EU countries on the total number of scholars and researchers attracted
- Number of new and underutilized food sources identified
- Number of scientific publications produced
- Number of citations
- Number of organized workshops
- Number of participants to the workshops
- Number of created Spin-offs
- Number of tested pilots, and percentage of successfully completed testing
- Number of new PhD students enrolled
- Number of new launched products (based on new technologies in food processing)
- Percent of reduced energy and waste consumption in production processes
- Number of submitted patents
- Months needed to set up new laboratory
- Number of realized educational activities for local actors
- Number of created dissemination products
- Number of collaborations with other Ecosystems and stakeholders outside the region at EU level

Grazie per l'attenzione