

VES4US A Horizon 2020-Future and Emerging Technology Project: Quality management based approach

Giovanna L. Liguori (1), Christopher Stanly (2), Giorgia Adamo (3), Samuele Raccosta(4) Darja Božič (5), Antonella Cusimano (3), Daniele Romancino (3), Rita Carrotta (4) , Vincenzo Martorana (4), Rosina Noto (4), Katharina Landfester (6), Blanca Rodriguez (7), Svenja Morsbach (6), Paolo Arosio (8), Elia Di Schiavi (2), Laura Corcuera (7), Nicolas Touzet (9), Mauro Manno (4), Gabriella Pocsfalvi (2), Ales Iglic (6), Veronika Iglic (6), Antonella Bongiovanni (3) and Annamaria Kisslinger (10)

(1) National Research Council of Italy (CNR), Institute of Genetics and Biophysics (IGB), Napoli, Italy;(2) CNR, Institute of Biosciences and BioResources (IBBR), Napoli, Italy; (3) CNR, Institute for Biomedical Research and Innovation (IRIB), Palermo, Italy;(4) CNR, Institute of Biophysics, Palermo, Italy;(5) Faculty of Health Sciences, University of Ljubljana, Ljubljana, Slovenia;(6) Max-Planck Institute for Polymer Research, Mainz, Germany;(7) Zabala Innovation Consulting, Navarra, Spain;(8) ETH Zurich Institute for Chemical and Bioengineering, Zurich, Switzerland;(9) Institute of Technology Sligo (ITSligo), Sligo, Ireland;(10) CNR, Institute of Experimental Endocrinology and Oncology (IEOS), Napoli, Italy

INTRODUCTION

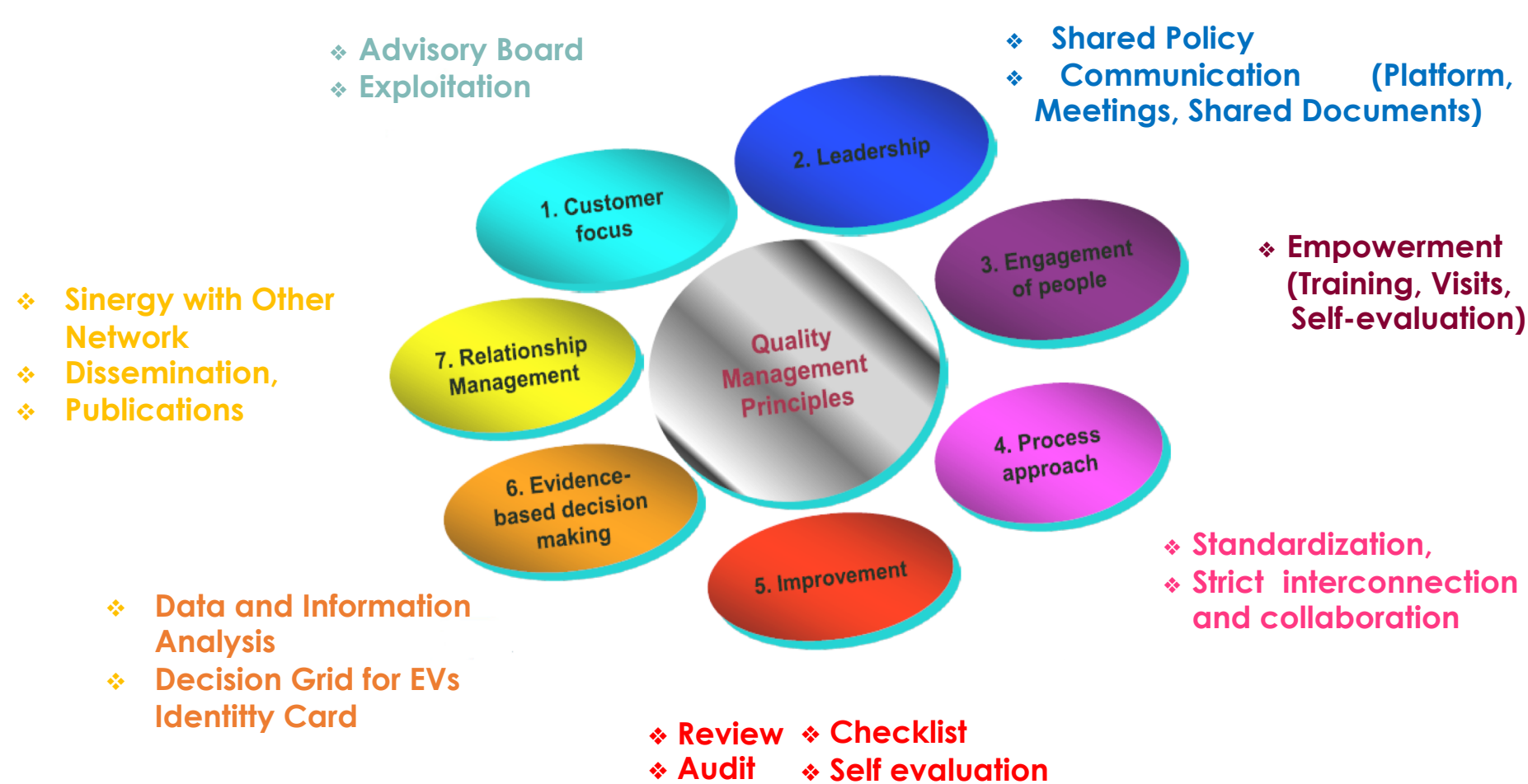
In recent years, the scientific world has been clearly experiencing a revolution: the attention of the scientific and social community is not focused solely on the final results, but also on the process utilized and other related issues such as the **reliability**, safety, and efficacy of the discoveries, the **research integrity** and the efficient and effective use of resources. **Quality management** might provide key tools to ensure valuable, robust and dependable outcomes, within a framework of best practice¹⁻³. Nowadays, different quality models have been developed in different countries and institutions and a quality approach represents an **added value** for research project proposals submitted for funding.

PURPOSE

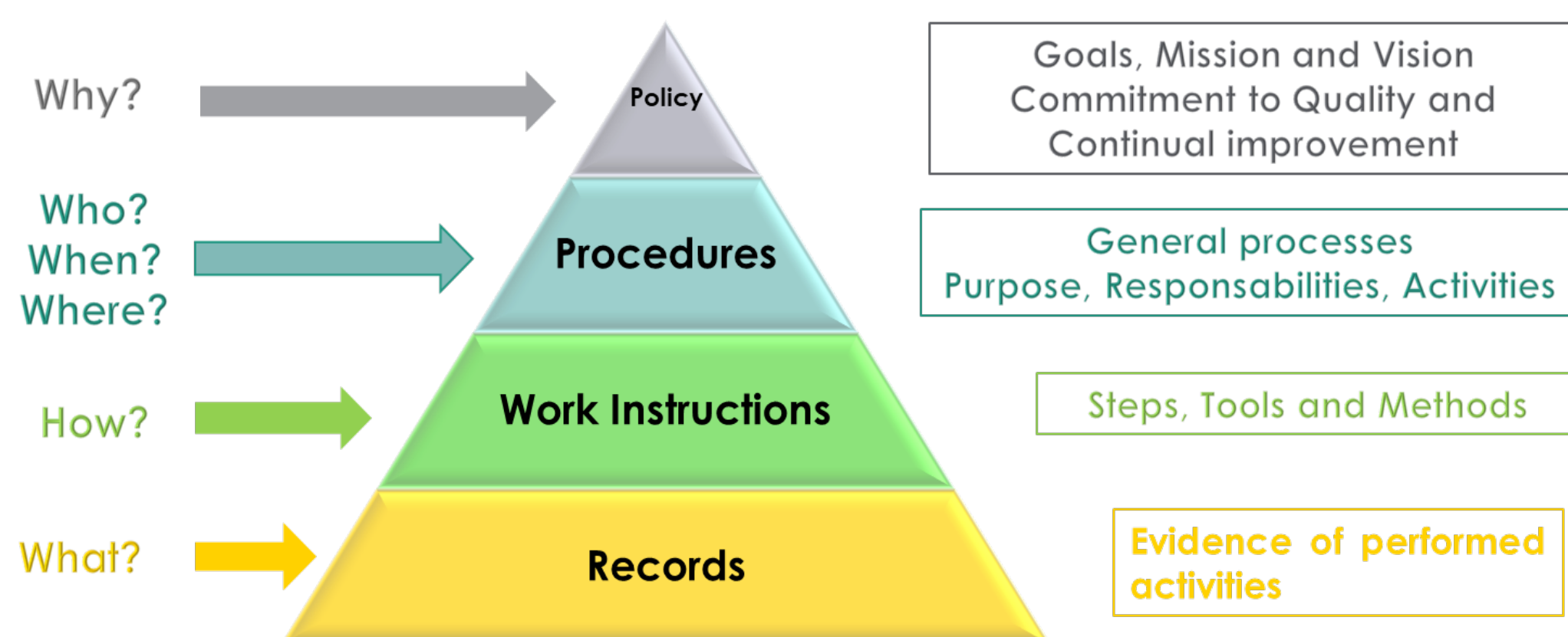
The **VES4US** consortium is a highly interdisciplinary and interconnected network, covering different research disciplines in a joint effort to develop an **innovative platform** for the efficient production of **extracellular vesicles** (EVs) from a natural source, and their use as **safe and efficient tailor-made nanocarriers**. Due to their high level of heterogeneity, specific issues arise when working with EVs, that need to be addressed to assure reliability and reproducibility of scientific data as well as the possibility of manufacturing at large scale. Therefore, one of the tasks of the project is specifically devoted to the definition of a **Quality management system (QMS)** fundamental for the identification and diffusion of **best practice, standardization of procedures, reproducibility and validation of the scientific results**.

QMS PRINCIPLES & PROCESSES

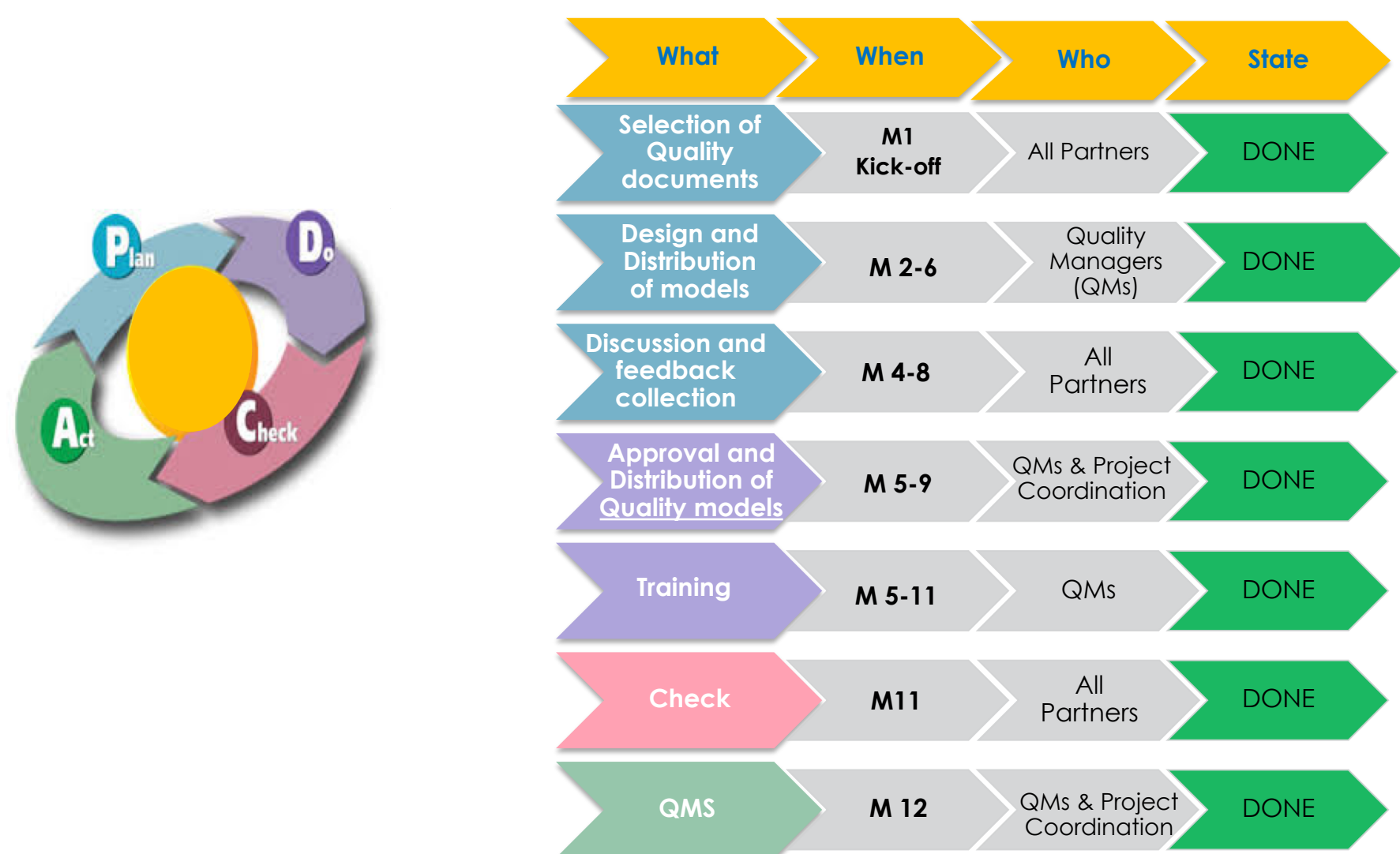
QMS Principles and Corresponding VES4US Actions



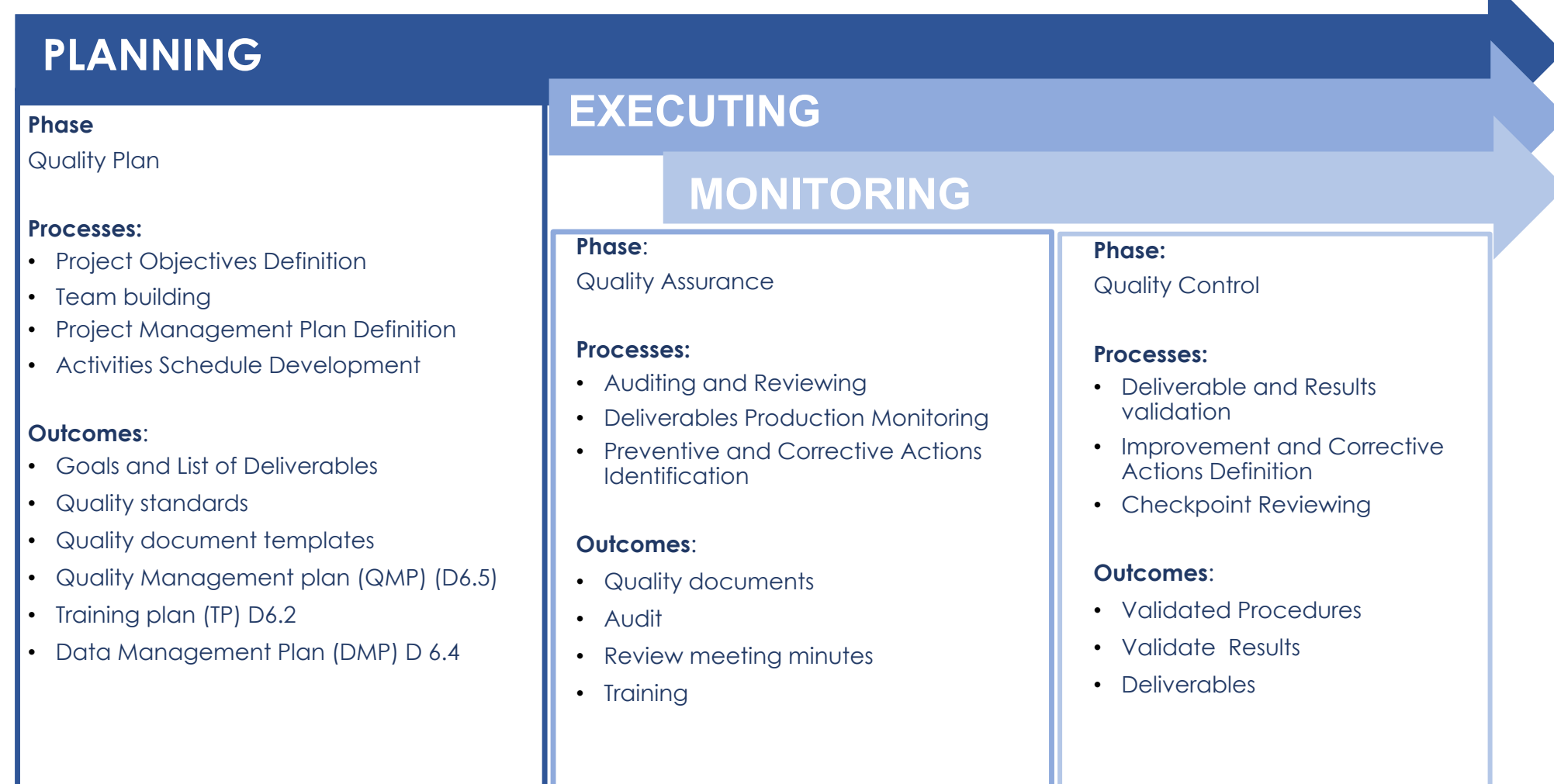
QMS Documentation



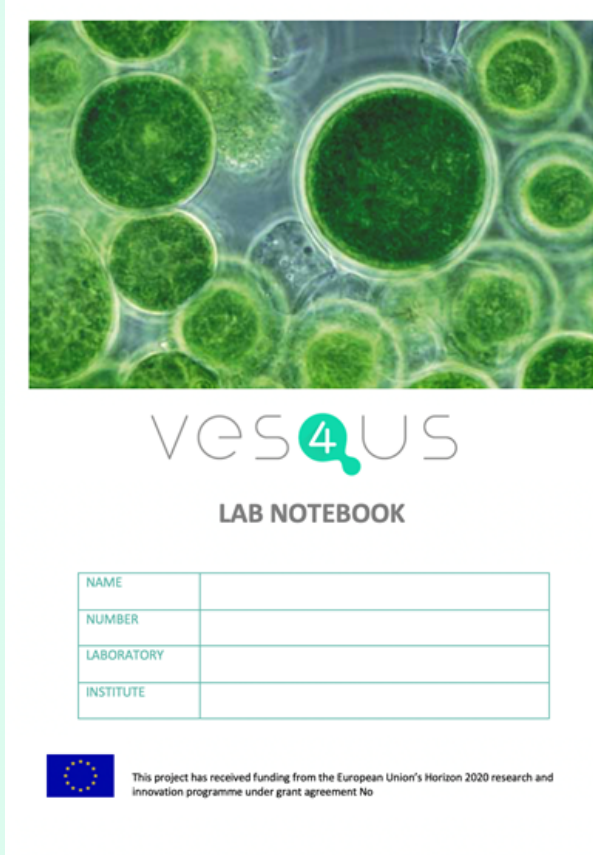
VES4US QMS Timeline



QMS_Processes

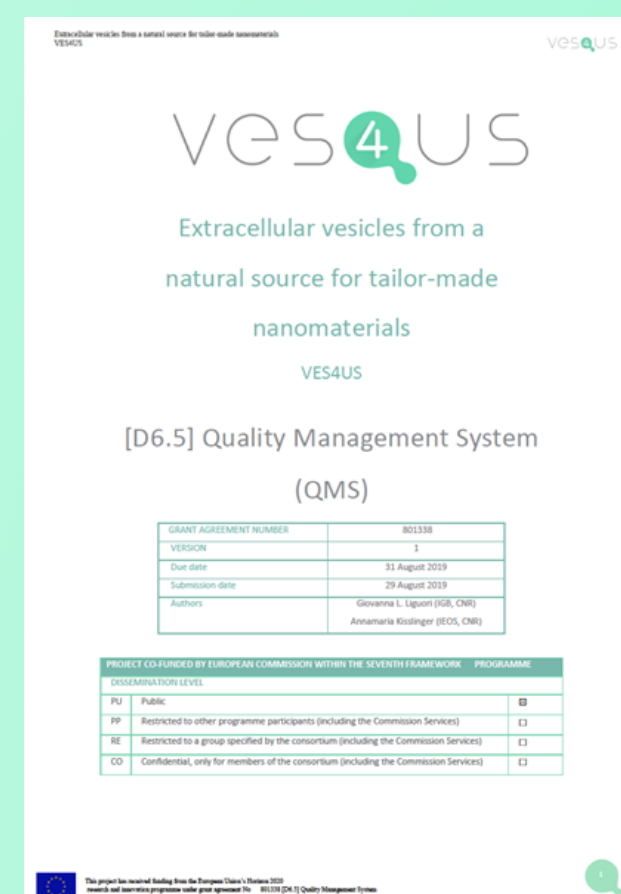


VES4US QMS TOOLS AND DELIVERABLES



LIST of SOPs

- Differential ultracentrifugation method for Extracellular Vesicle Enrichment (CNR-IRIB) DONE
- Microalgae cultivation for EVs production (ITS) IN PROGRESS
- Gradient ultracentrifugation for the purification of EVs (CNR-IBBR) IN PROGRESS
- Size distribution of labelled EVs through Fluorescence Correlation Spectroscopy experiments (CNR-IBF) IN PROGRESS
- In-solution protein digestion of EV samples for mass spectrometry-based proteomics application (CNR-IBBR) IN PROGRESS
- Liposome preparation as EV model system and their functionalization with DBCO groups (MPIP) IN PROGRESS
- In liquido culturing of C.elegans in 96- and 384-well plates and analysis of extracellular vesicles uptake (CNR-IBBR) (IN PROGRESS



11. LIST OF ANNEXES

- Quality and Project Management Templates
- Lab Notebook Template
 - SOP for Scientific Activities Template
 - SOP for Project Management and Support Activities Template
 - Deliverable Template
 - Meeting Agenda and Minute Template
 - Timesheet Template
- Quality Assurance and Quality Control Templates
- Lab Notebook Template Checklist
 - SOP Template Checklist
 - SOP Checklist
 - Deliverable Checklist
 - Audit Template

CONCLUSIONS

- VES4US QMS is an agreed QMS with a light, dynamic and research oriented structure to guarantee standardization of procedures not at the expense of research creativity and freedom**
- VES4US QMS provides a description of the approach and methodologies implemented within the Project to ensure quality, consistency and reliability of the results**
- Our final goal is to develop a Quality Management Operating Model for high interdisciplinary and innovation research projects**

References: (1) Bongiovanni A., Colotti G., Liguori G.L., Di Carlo M., Digilio F.A., Lacerra G., Mascia A., Cirafici A.M., Barra A., Lanati A. and Kisslinger A. Applying Quality principles and Project Management methodologies in biomedical research: a public research network's case study. (2015) AQA 20, 203–213; (2) Digilio F.A., Lanati A., Bongiovanni A., Mascia A., Di Carlo M., Barra A., Cirafici A.M., Colotti G., Kisslinger A. Lacerra G., Liguori G.L. Quality-based model for life sciences research guidelines. AQA 21,221–230 (2016); (3) Mancinelli S., Zazzu V., Turcato A., Lacerra G., Digilio F.A., Mascia A., Di Carlo M., Cirafici A.M., Bongiovanni A., Colotti G., Kisslinger A., Lanati A. and Liguori G.L. Applying Design of Experiments methodology to PEI toxicity assay on neural progenitor cells. Mathematical Models in Biology Springer (2015).