

*Introduction:*

# *“Molecular Pathology Standardization”*

*Giorgio Stanta*

*The OEI Biobanking and Molecular Pathobiology WG to obtain more reproducible and exchangeable diagnosis and clinical research is collaborating with several European Organizations:*

### *With Cancer Organizations:*

*Courses*

**EACR**

European Association  
for Cancer Research

*Patients*



European Cancer  
Patient Coalition

*Molec. Pathol.*

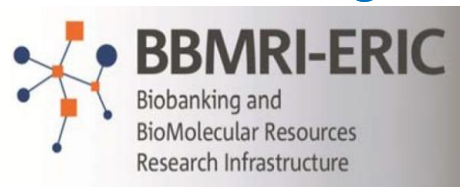


European  
Society of  
Pathology

Molecular Pathology WG

### *With other Organizations:*

*Biobanking*



Quality Expert  
Working Groups

*Standardization Master*



European  
Committee  
Standardization



Union Europeenne  
des Medicines  
Specialistes

*Clinical Tiss. Anal.*





## European Molecular Pathology Master Steering Committee

*Alfredo Ariza Fernandez (Spain)*

*Karl-Friedrich Becker (Germany)*

*Serena Bonin (Italy)*

*Leonor David (Portugal - EACR rep.)*

*Ambrogio Fassina (Italy)*

*Falko Fend (Germany)*

*Pedro L. Fernández (Spain)*

*Paul Hofman (France)*

*Gerald Höfler (Austria)*

*Michael Hummel (German Mol Path Diploma)*

*Marius Ilie (France)*

*Mohammad Ilyas (UK)*

*Andreas Jung (Germany)*

*Annette Lebeau (Germany)*

*Karin Oien (UK)*

*Henrique Rui (Portugal)*

*Ed Schuurin (Dutch Mol Path Diploma)*

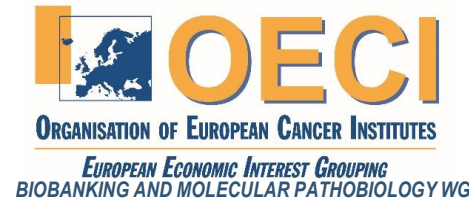
*Giorgio Stanta (Italy - Chair)*

*Dina Tiniakos (UK)*

*Emmanuelle Uro-Coste (France Mol Path Diploma)*

Organisation of European Cancer Institutes - EEIG





## European Molecular Pathology Master

*#The master was chosen as a modality **to standardize diagnostic molecular pathology in Europe**. This is not possible in the specialization schools because of different programs in different countries and a low level of plasticity.*

*# The steering committee of the master (people in charge of molecular pathology initiatives in different countries) can modify the program continuously allowing the **diagnostic molecular pathology to be always updated and standardized**.*

*#The program is **based on the already developed experience** of the French diploma and the evaluation of it based on other existing courses and diplomas in Europe such the ones in Netherlands and Germany.*

*#As today **diagnostic molecular pathology is directly connected to diagnostics and treatment, the standardization of the analyses is a basic requirement** to make them reproducible and exchangeable among European health institutions.*

*#The **standardization is based on the European specific projects**.*





# European Molecular Pathology Master

**Rationale:** This Master course is established in response to the extremely urgent need at the European level to perform **reproducible and exchangeable molecular diagnostic analysis**. Today when exchanging a clinical record from one hospital to another we are never sure about the same meaning of the molecular diagnostic results.

This is even more pressing because of the continuously increased use of **diagnostic, prognostic and predictive biomarkers, directly related to treatment choices**.

Other types of more sophisticated techniques are now used at the molecular level with a **continuous rapid development**.

**Interpretation of results** of diagnostics and clinical research molecular analysis are increasingly complex.

The master will be open to **pathologists**.

Recent decisions taken inside the European Commission Committees (ECIBC) pointed out the **importance of clinical research performed directly on today patients** for today patients and the collection of big data.

This means the necessity of the development of excellent centers for cancer and the **preparation of new professionals**.

**Objectives:** -EMPM will guarantee **practical training** in the field of molecular pathology diagnostics and clinical research especially in the fields of oncology but also in infectious diseases with a common European language. In the future other issues can be developed.

-Theoretical and technical aspects will be covered.

-Diagnostic interpretation will be included for all the main diagnostic areas of pathology.

-Quality assurance will be one of the main issues to guarantee reproducibility and exchangeability of the results.

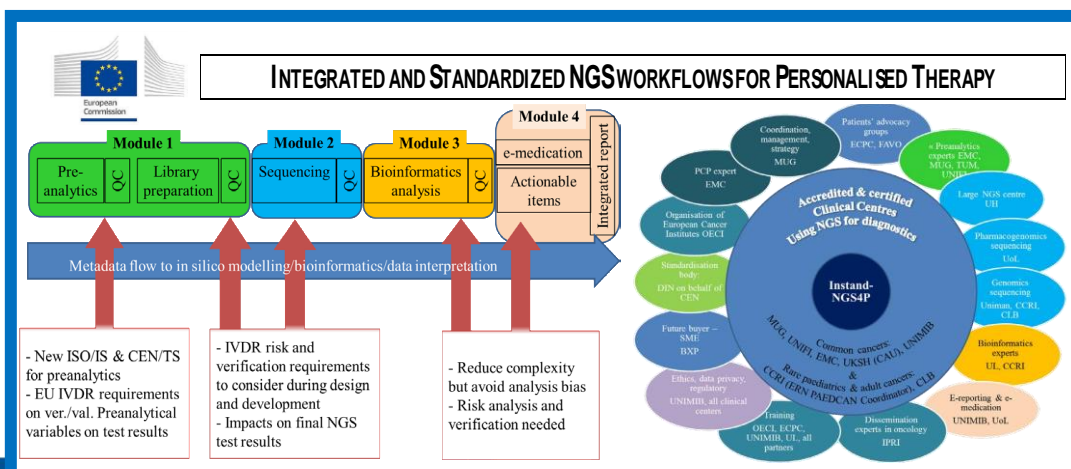
-Bioethical aspects will be considered with evaluation of the different rules in Europe.

-Bioinformatics and AI aspects will be considered.





*HERCULES : HETEROGENEITY “Comprehensive characterization and effective combinatorial targeting of high-grade serous ovarian cancer via single-cell analysis”.*

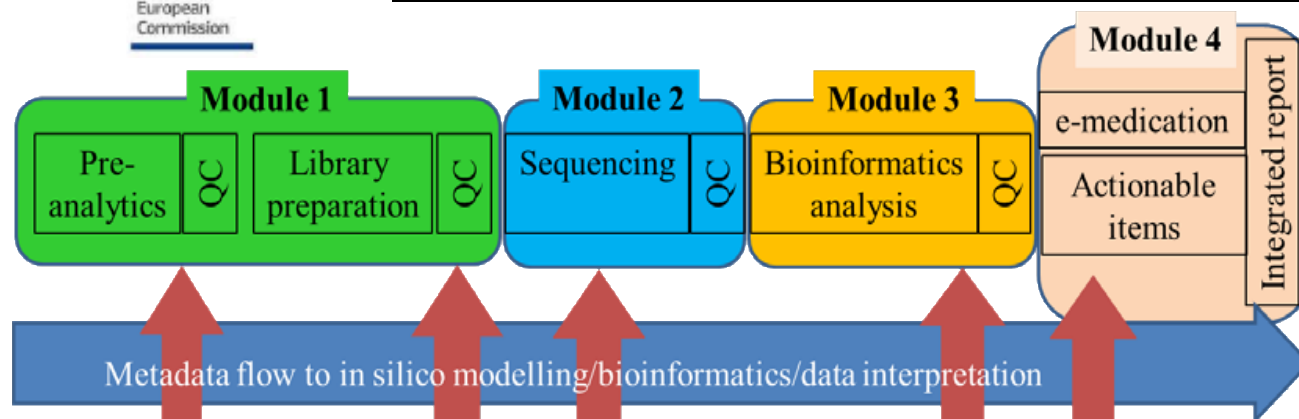


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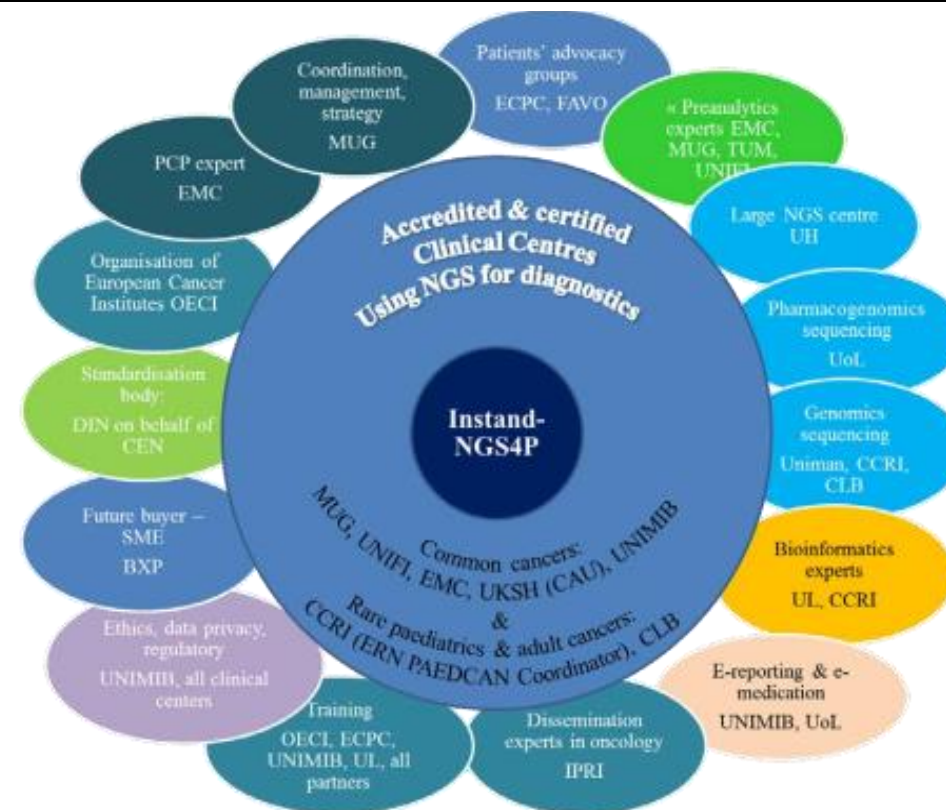
# INTEGRATED AND STANDARDIZED NGS WORKFLOWS FOR PERSONALISED THERAPY



- New ISO/IS & CEN/TS for preanalytics  
- EU IVDR requirements on ver./val. Preanalytical variables on test results

- IVDR risk and verification requirements to consider during design and development  
- Impacts on final NGS test results

- Reduce complexity but avoid analysis bias  
- Risk analysis and verification needed





# Instand-NGS4P



Co-funded by the European Union

Grant Agreement n° 874719

*To develop the activities of validation, communication and dissemination within WP5. OEI has a great expertise in communication and dissemination tools:*

*#OEI website [www.oeci.eu](http://www.oeci.eu)*

*#OEI Magazine – bi-annual Published by OEI*

*#OEI Yearbook published each year and containing special announcement related to the main activities/project*

*#Specific publication of [ecancer](#), the OEI Official Journal - open-access journal (in English and Spanish)*

*#Specific Sessions or round tables at the Annual OEI Event: OEI Oncology Days*

*#Communications sent to the European Cancer Organisation [www.ecco-org.eu](http://www.ecco-org.eu)*

*#Specific pages published on Cancerworld [www.cancerworld.net](http://www.cancerworld.net)*

*#OEI affiliated Review “TumorJournal”, <https://journals.sagepub.com/home/tmj>*

*#Concerning the validation process, OEI has already discussed a process of rapid validation of biomarkers, targets and methods through the collaboration of OEI Certified Comprehensive Cancer Centres and Clinical Cancer Centres.*

*#Possibility to introduce the project results in the OEI accreditation process*



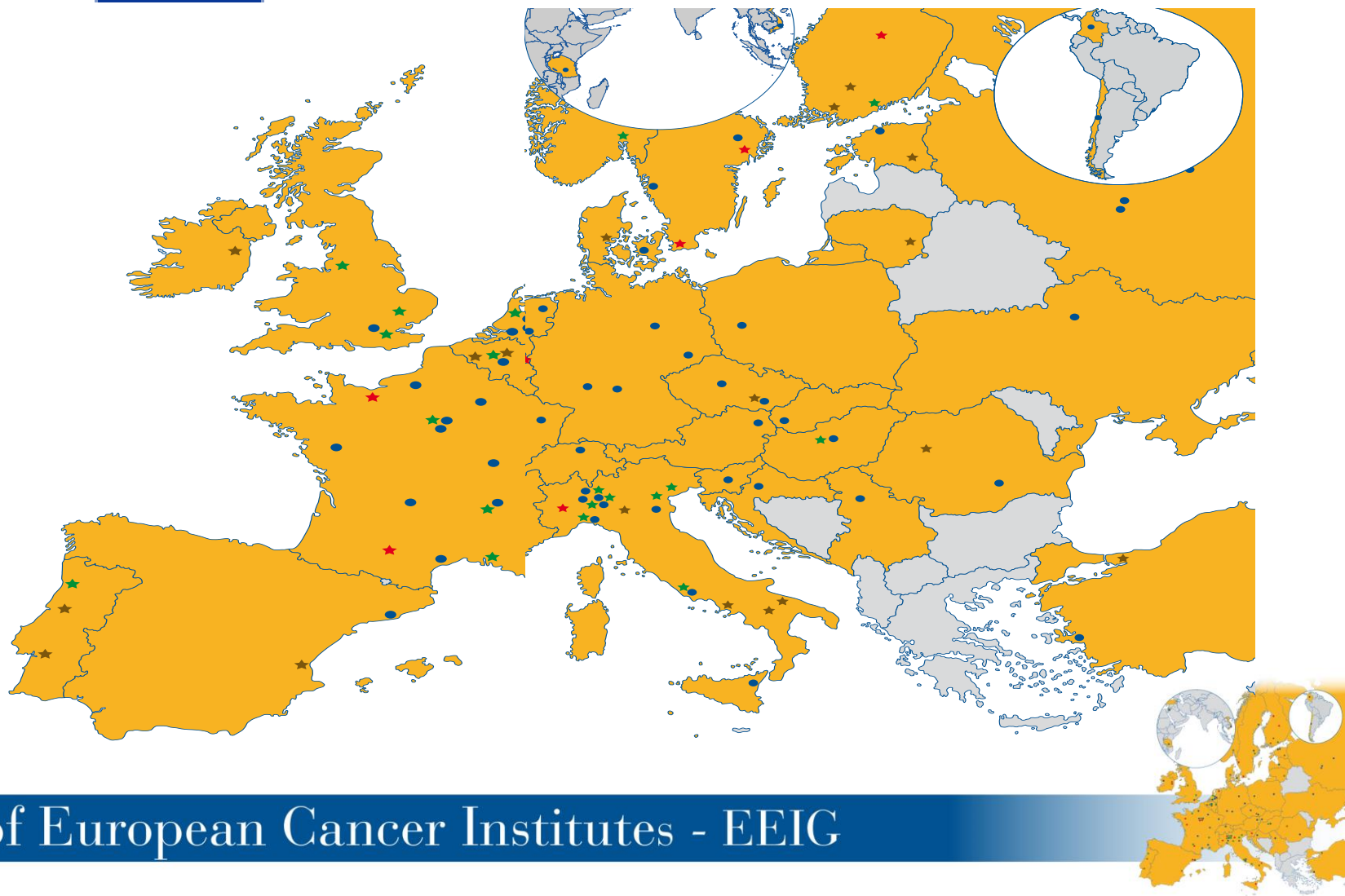


# Instand-NGS4P



Co-funded by the European Union

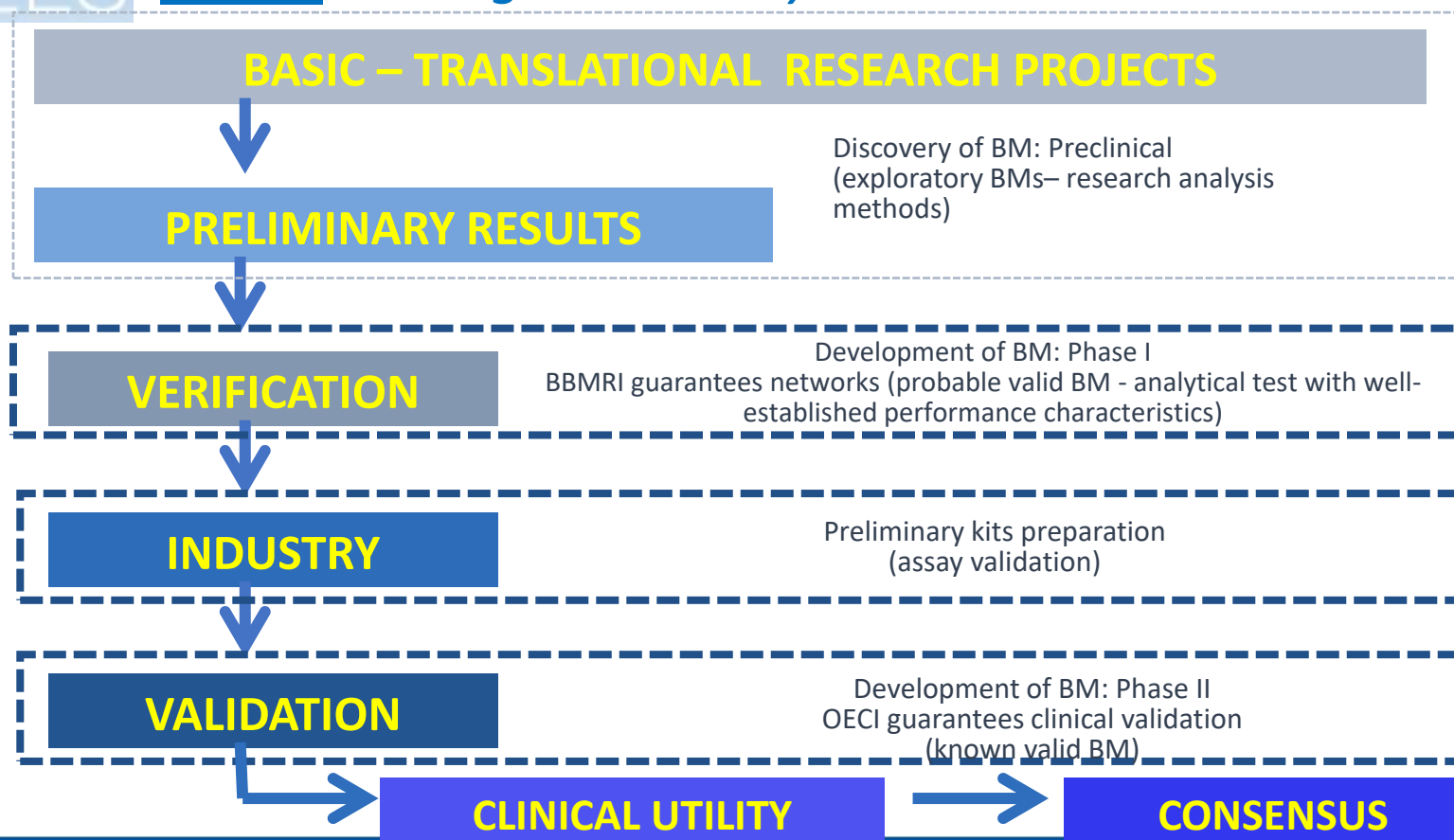
Grant Agreement n° 874719



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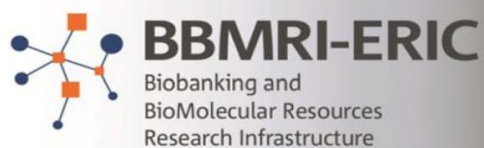


*HERCULES (EU project 667403) on “Comprehensive characterization and effective combinatorial targeting of high-grade serous ovarian cancer via single-cell analysis”.*



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*Quality Expert Working Groups*



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