

1. PUBLISHABLE SUMMARY

Summary of the context and overall objectives of the project (For the final period, include the conclusions of the action)

Started on January 1st, 2017, the goal of the 48-month project SPIDIA4P (Standardisation of generic Pre-analytical Procedures for In vitro DIAGnostics for Personalised Medicine; www.spidia.eu) is to go the next steps towards healthcare systems improvements with worldwide impact by developing and implementing a comprehensive portfolio of 22 European pre-analytical CEN/Technical Specifications (CEN/TS) and ISO/International Standards (ISO/IS), addressing the important pre-analytical workflows applied to personalised medicine. These CEN/TS and ISO/IS will also be applicable to biomedical research and to biobanks. The standard documents are thus applicable to all segments and the entire value chain which contribute to biomarker discovery, development and implementation into healthcare: high quality samples in biobanks as the decisive basis for all biomarker related work, biomedical research in the industry and other research institutions to develop biomarkers including generation of scientific evidence for these, in-vitro diagnostic (IVD) test development, and implementation and use of these IVD tests in healthcare systems. Furthermore, corresponding External Quality Assurance (EQA) Schemes will be developed and implemented by SPIDIA4P as well, aiming to survey the resulting diagnostic practice. SPIDIA4P will ensure training, education, and counselling as additional major foci of the project.

SPIDIA4P's highly successful predecessor SPIDIA laid the basis for developing and introducing the first 9 CEN/TS for pre-analytical workflows into European countries and initiated their progress to ISO/IS documents. Like SPIDIA, the current SPIDIA4P project is bringing together key experts of numerous stakeholder organisations with deep knowledge on pre-analytical and analytical procedures, European and international standardisation organisations' processes (CEN and ISO), external quality assurance, quality management, ethics and regulatory demands.

SPIDIA4P is funded as a coordination and support action by the European Union's Horizon 2020 research and innovation programme and consists of 19 highly experienced partners from private industry including SMEs, public institutions and the European Standards Organisation CEN.

The SPIDIA4P consortium is closely interacting with various large European public research consortia to obtain access to research and validation studies data, serving as evidence for the new joint standards developments for achieving improvements of diagnosis, patient stratification and prognosis of disease outcome. Based on the success of SPIDIA coordination, QIAGEN has been renewed as Coordinator unanimously.

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far (For the final period please include an overview of the results and their exploitation and dissemination)

During the first 18 project months, SPIDIA4P started the project work for all intended 14 new CEN/TS and ISO/IS documents (for details, please see "Biobanks Europe, Issue No. 6/2017": http://www.bbmri-eric.eu/wp-content/uploads/2017/02/2017_Newsletter6_7_WEB.pdf). This work is progressing at the CEN/Technical Committee (CEN/TS) 140 for "In vitro diagnostic medical devices" and at the ISO/TC 212 for "Clinical laboratory testing and in vitro diagnostic test systems".

The new documents will complement the existing and already published CEN/TS documents, which were originally initiated by SPIDIA, and which are on their way to become ISO/IS documents soon (for details, please see on the SPIDIA / SPIDIA4P website: <http://www.spidia.eu/publications/spidia-publications/technical-specifications/>).

SPIDIA4P has also started to develop and implement EQA Schemes, corresponding to the published SPIDIA CEN/TS documents and to the new upcoming SPIDIA4P CEN and ISO documents, aiming to survey the resulting diagnostic practice. During the first 18 project months, the first 10 EQA Schemes were finally tested by SPIDIA4P consortium participants as well as by broader international communities. Results will be published soon.

SPIDIA4P has started a quite huge portfolio of measures for the implementation and dissemination of standards and EQA Schemes. During the first 18 months, these included updates on the SPIDIA4P website (www.spidia.eu), several social media campaigns, a first Newsletter sent to more than 16,000 recipients, development and release of a first wave of e-education and e-learning/teaching materials, several training courses, a digital self-assessment tool for the assessment of the compliance of pre-analytical procedures with the published CEN/TS and the upcoming related ISO/IS documents, intensive presence at international conferences with more than 20 mostly invited talks, meetings with professional societies, and finally publications (<http://www.spidia.eu/publications/spidia4p-publications/>). More details will be become public during the progression of the SPIDIA4P project.

Progress beyond the state of the art, expected results until the end of the project and potential impacts (including the socio-economic impact and the wider societal implications of the project so far)

At its funding period end in 2020, SPIDA4P expects to have generated and implemented the comprehensive portfolio of 22 pre-analytical CEN/TS and ISO/IS documents listed above, addressing the important pre-analytical workflows applied to Personalised Medicine. Corresponding EQA Schemes will have been developed and implemented as well, aiming to survey the resulting quality of samples and diagnostic practice.

Diagnostic errors cause about 10% of all patient deaths and about 17% of adverse events [Institute of Medicine (IOM) Report Sept. 2015]. Based on SPIDIA's broad evidence, it is expected that these CEN/TS and ISO/IS documents and their associated EQA Schemes will significantly contribute to the sustainability of health care systems by reducing the number of diagnostic errors. The standards are of key importance as pre-analytical workflows contribute by about 50 – 70% to the diagnostic errors rate [e.g. Medical Laboratory Observer; May 2014]. Securing good quality clinical samples with molecular bioanalyte profiles as they were in the patient's body, is decisive for most of the applications in Personalized Medicine. Most of the analytical tests and applications will therefore benefit on pan-European and local scale.

SPIDIA4P's work has become also important in light of the new EU "in vitro diagnostic medical devices regulation (IVDR)" which was released in May 2017 with a 5 year' transition period (REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL). This new law contains dedicated requirements for pre-analytical workflow variables in various paragraphs. The CEN/TS and ISO/IS documents as well as the EQA Schemes are expected to become quite relevant for translating these requirements into daily routine.

Overall, the expected reduction of diagnostic errors will lead to improved patient stratification in Personalized Medicine, prognosis of disease outcome, improved clinical decisions and health outcomes for the benefits of patients.

As the CEN/TS and ISO/IS documents are also applicable to research and biobanks, it can be expected that the too high percentage of non-reproducible research studies will be reduced. This will lead to faster growth and benefits to the European diagnostics industry, also to SMEs working on new biomarkers and new services.

Address (URL) of the project's public website

<http://www.spidia.eu/>



Figure 2: European Conference "Standards: Your Innovation Bridge", Brussels (2014), SPIDIA Booth