**Sniff-Nose**: A novel double-point intravascular diagnostic probe with continuous monitoring of the biomarker panel, dual oxygen tension PcvO2 and PcsO2, for clinical assessment of heart failure

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No [697004]

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Topic: PHC-12-2015-1 Clinical research for the validation of biomarkers and/or diagnostic medical devices

**Publishable Summary**

The SME Instrument Phase 1 ***Sniff-Nose*** dual-oximetry measurement project led us to the identification of a very promising business opportunity in the field ***heart failure monitoring***.

As a result we generated a business plan within the Phase 2 approach, supported together with an R&D report and an R&D plan for Phase 2.

The work performed according to Task 1 to Task 15 of Phase-1 includes:

1. successful validation of the double-point oxygen measurement in the lab;
2. generation of an R&D plan for Phase 2;
3. clinical KOLs identified with opinion surveys conducted;
4. main risk assessment fulfilled ISO 14971 requirement;
5. regulatory strategy leading to CE marking created;
6. establishment of a clinical investigation strategy with highly-reputed Heidelberg University Hospital, in accordance with ISO-14155-rules for clinical investigation;
7. IPR management strategy planned with the assistance from the European project, Fit for Health 2.0, to ensure sustainable freedom-to-operate;
8. market research done containing a detailed competition analysis;
9. identification of health insurance reimbursement possibility (with established DRG figures achieved by a US competitor) leading to market viability;
10. marketing and sales strategy planned;
11. financial planning done with a budget fitting within Horizon 2020 also with assistance from Fit for Health 2.0;
12. strategic decision to add pressure measurement to the devices as it improves the value of the information collected on the patient;
13. successful search for a partner. emka TECHNOLOGIES (MKT), in Paris, a company with experience in implanted devices, was identified to join for Phase 2 as consortium coordinator;
14. a business plan for Phase 2 was established aiming at setting up a joint venture with MKT to market and sell the devices. Plan includes P&L and cash estimates covering Year 2017 to 2019.

The Phase 1 results reached the following conclusions to be implemented in Phase-2:

1. Decision by MI and MKT to join their complementary strengths,
2. Decision to design a product family, named ***Cor/log***, simultaneously measuring oxygen in 2 locations as well as central venous pressure;
3. All of the above leading to the key decision to set-up an **ambitious joint venture to market and sell the devices** to monitor heart failure patients.
4. This joint venture will be initially funded by MI and MKT with help of Phase-2 grant, with private investors expected to join as soon as clinical trials confirm the product viability.