Grant Agreement no. 287596

d-LIVER

ICT-enabled, cellular artificial liver system incorporating personalized patient management and support

INSTRUMENT: Collaborative Project (Integrating Project)

OBJECTIVE: ICT-2011.5.1

D9.4 Qualitative Market Analysis – Publishable Executive Summary ONLY

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Dissemination Level		
PU	Public	
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including Commission Services)	
CO	Confidential, only for members of the consortium (including Commission Services)	✓

Publishable Executive Summary

Based on information provided by the Exploitation Committee and the clinical partners of the d-LIVER project and an in-depth assessment, this document analyses the different aspects that are relevant for the market perspective for the *overall d-LIVER system*, it gives an overview on competing systems and competing research work, and includes a collection of market and product data available. It focuses on the overall system with the following key aspects:

- Patient monitoring (wearable devices and blood/liver monitoring)
- Bio-artificial liver (BAL)

The patient monitoring system consists of the wearable sensors and the blood biochemistry instrument (BBI). It is assumed that these two systems will be used together by the patient. In addition, the BBI uses a disposable cartridge to perform the blood tests typically once per day. We have assessed the relevant wearable devices that are available on the market and also the state-of-the-art and availability of relevant continuous monitoring devices.

The bio-artificial liver provides therapy for the liver patient. Each system needs to be prepared using live cells specifically for each patient. Here we have assessed a large number of existing bio-artificial and non-biological (artificial) Liver Support Systems with regards to concept/technology, development state and progress in terms of results and trials.

Point-of-care (PoC) is a rapidly growing market with many research activities world-wide but despite the high expectations, there are only very few commercial products available so far. In regards to the solution that we develop within d-LIVER, the following assessments and conclusions have been made:

- Patient monitoring system: more and more wearable sensors and systems have been developed in recent years and there is a significant hype in realising new solutions that work with mobile devices/phones. However, no commercial wearable device currently measures parameters like blood pressure as needed for d-LIVER. Also no specific commercial chronic liver monitoring devices have been found on the market. Current patients are predominantly monitored by symptoms and blood testing for standard liver functions.
- Regarding the bio-artificial liver, none of the current systems have shown to improve survival at statistically significant levels, even though some have achieved improvement in patient subsets. Our research shows that it has been difficult so far to demonstrate utility in clinical trials and generally very poor improvement in health of patients has been demonstrated.

In terms of market figures, we take into account that in the EU we have approximately 70,000 people dying from chronic liver disease each year and approximately 6,000 liver transplants each year. A reasonable market size for liver monitoring and support might then be estimated, across the EU, as about 20,000 – 25,000 individuals (with growing numbers). Data on health economics is currently being collected/assessed. This will provide additional data for the prediction of possible markets of the d-LIVER system.

By the end of the d-LIVER project, a final exploitation plan and technology roadmap will be elaborated.

Note: All further pages of this document are confidential.