



**ICT-ENABLED, CELLULAR
ARTIFICIAL LIVER SYSTEM
INCORPORATING PERSONALIZED PATIENT
MANAGEMENT AND SUPPORT**

10/2011 – 09/2015

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d-LIVER: Why? A clinical perspective

The problem

- ◆ End-stage liver diseases (ESLD) associated with high risk to patients
- ◆ ESLD also associated with very poor quality of life, particularly through the complication development
- ◆ Current monitoring and management models are a poor compromise (not dynamic but still sufficiently burdensome to impact negatively on patients)



d-LIVER: Why? A clinical perspective

The vision behind d-LIVER

- ◆ To use technology to move management of ESLD patients out of the clinic and into the home or near-home setting
- ◆ To improve **quality** and **length** of life by dynamic management of complications (daily not monthly)
- ◆ To improve **quality** of life for patients and carers through avoiding burdensome clinic visits
- ◆ To reduce **cost** of management by earlier, cheaper intervention



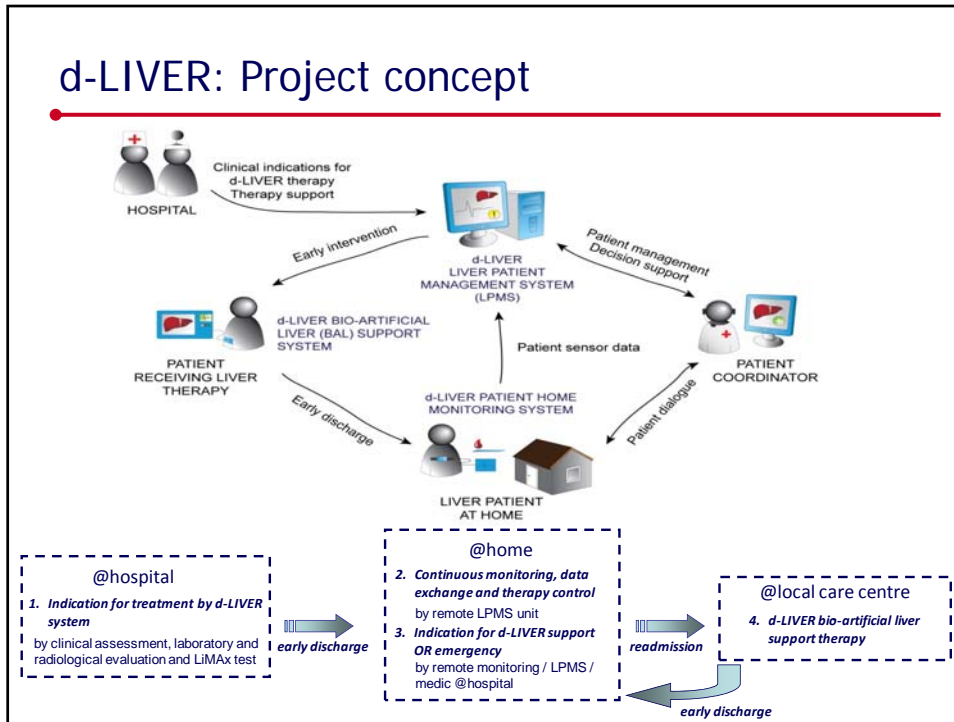
d-LIVER: Clinical delivery of project vision

Delivered by 4 scenarios

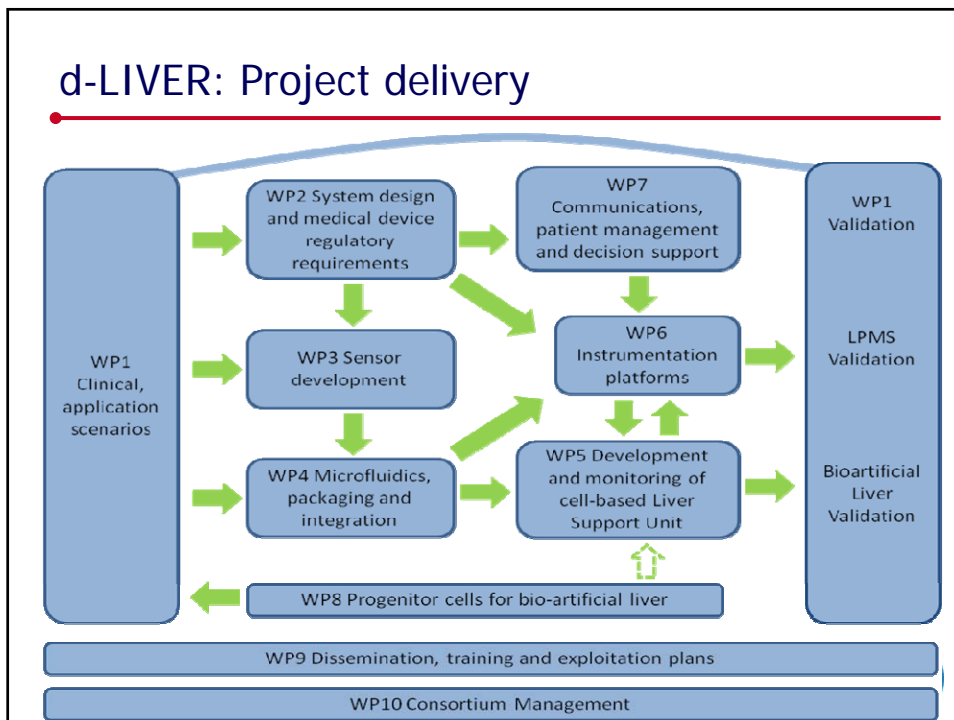
1. Chronic liver failure: – treat "acute on chronic liver" failure, reduce intermittent encephalopathy, enable long-term therapy in home environment and reduce need for transplantation
2. Chronic cholestatic itch: – intermittent long-term therapy to reduce cholestatic itch, to extend time before transplantation is inevitable, to improve quality of life
3. Bridging therapy before liver transplantation: – therapy for high-risk patients to reduce duration and incidence of hospitalization and thus waiting-list mortality
4. Acute liver failure: – e.g. "small for size" syndrome to support liver function when resected liver proves insufficient



d-LIVER: Project concept



d-LIVER: Project delivery



d-LIVER: Remote patient monitoring

Monitoring of	Parameters included
Patient characteristics	- weight - temperature - cognitive tests such as "Trail-making" - pain
Liver function	- bilirubin - ammonia - bile acids - albumin - clotting time
Renal function and electrolyte homoeostasis	- creatinine - sodium - potassium
Neurological	- encephalopathy - interactive neurological tests
Cardiac (for high risk)	- heart rate - blood pressure

d-LIVER: Bioartificial liver support

- ◆ Metabolic liver function can only be provided by living cells
- ◆ The project will develop a cell-based bio-artificial liver (BAL) support system for transient therapy of liver patients
- ◆ BAL will include integrated sensors to monitor and control cell viability and quality

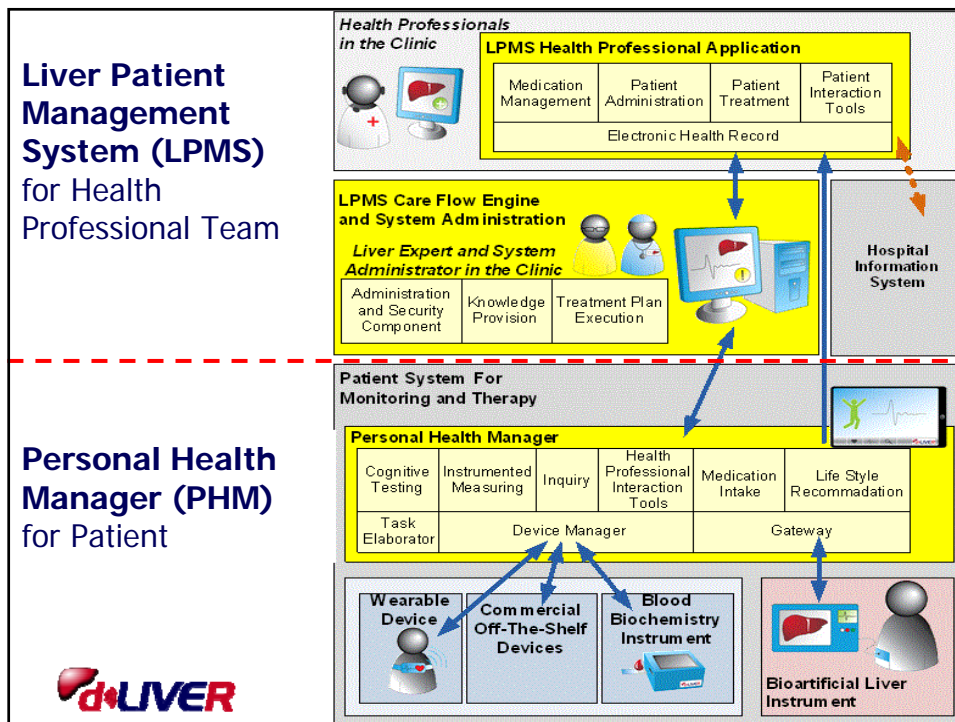


In a parallel, high-risk, activity the project will seek to produce human hepatocytes from pancreatic progenitor cells which would be ideal for use in the BAL since they could provide an unlimited supply of functional hepatocytes, thus overcoming drawbacks associated with both primary hepatocytes and stem cells

d-LIVER: ICT aspects

The ICT aspects of d-LIVER follow three strands:

1. Remote monitoring of patients with chronic liver disease
 - ✦ Wearable sensors will be developed to monitor the physical indicators of patient health status at home using clinically relevant parameters
 - ✦ A blood biochemistry instrument will perform discrete biochemical analyses of essential metabolites in blood
2. Monitoring and communication associated with the BAL
 - ✦ A closed-loop system will be implemented to allow autonomous monitoring of both biochemical and biophysical parameters affecting cell environment and function, such that the patient detoxification session can be personalised and optimised
3. Interoperable communication between the patient sensor network, the BAL and hospital information systems
 - ✦ The LPMS provides general remote feedback on patient status to clinicians for disease management and will also schedule patient treatment and clinic-based remedial actions using specially adapted triaging software



d-LIVER: Personal Health Manager

Personal Health Manager – Planned User Interface



Standards adopted



The most relevant standards adopted according to Continua Health Alliance guidelines are:

- ISO/IEEE 11073-104xx:yyyy, "Health informatics -- Personal health device communication -- Part 104xx: Device specialization"
- ISO/IEEE 11073-20601:2010, "Health informatics -- Personal health device communication -- Part 20601: Application profile -- Optimized exchange protocol"
- IHE Patient Care Device Technical Framework, Volume 1 (PCD TF-1) Integration Profiles
- IHE IT Infrastructure Technical Framework, Volume 2
- HL7 Messaging Standard Version 2.6



d-LIVER Technical Review,
Brussels, December 2012



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