1. PUBLISHABLE SUMMARY

AVERT-IT Project

Avert-IT is an EU-funded project to develop a mechanism, for use within intensive and high-dependency care units, which will have the ability to monitor and predict the likelihood of arterial adverse hypotension events. The full project title is *"Advanced Arterial Hypotension Adverse Event prediction through a Novel Bayesian Neural Network"* and will run for three years, beginning in January 2008.

Background

Intensive Care patients can experience Adverse Events associated with sudden episodes of low blood pressure. These Adverse Events may impact all of the main organs resulting in longer lengths of stay, increased care costs and reducing quality of outcomes. Existing technologies enable clinicians to know when these events have occurred and treat the effects.

Medical techniques for avoiding Adverse Events currently exist, but clinicians don't have a reliable way to predict the occurrence, so there's no opportunity for intervention.

Research indicates average lengths of stay can be reduced by up to 30%, and outcomes improved for a similar proportion of patients, if these Adverse Events can be avoided through prediction and intervention. Potential savings across the EU exceed 5 billion euros, annually.

A model for predicting Adverse Events offers potential for improving outcomes across a wide range of conditions and or illnesses.

Objectives

The main scientific objective of the project is the determination of the weighted association between multiple patient parameters and subsequent arterial hypotension. The association will then be used to define the novel Bayesian neural network, which will be trained against the BrainIT dataset, before undertaking a clinical trial to demonstrate the Avert-IT project concept.

The main technological objective will be the development of an IT-based decision support system (*"HypoPredict"*) appropriate for deployment within intensive and high dependency care units. The system will be capable of:

- Automatically and continually monitoring at least four in-vivo patient parameters (eg: ECG, arterial blood pressure, Oxygen saturation and core temperature), together with open interfaces providing input of key demographic data (age, gender etc.) and periodic data (clinical pathology results etc.) related to the patient.
- Outputting a continuous Hypotension Prediction Index (HPi) which will be updated on a minute by minute basis upon any change detected in the patient parameter input set.

Resources

The resources in terms of data, technology and expertise for the project will be combined from a variety of areas:

- Historic patient care data from 22 specialist brain injury units across Europe.
- Grid technologies for secure data access across multiple specialist units and hospitals.
- Baysian Artificial Neural Network (BANN) techniques for analysing data.
- Specialists in treating Traumatic Brain Injury (TBI) from 6 leading hospitals, in Sweden, Germany, Italy, Spain, Lithuania and Scotland.
- C3 Global's expertise in device monitoring, data analysis and reporting, and software development, distribution and support.

Outputs

The project will also look to develop an exploitation model for the commercialisation of the software in product/service sales across international markets. For such commercial exploitation, C3 Global will have exclusive access to the results of the research. Potential opportunities include:

- Monitoring of intensive care patient treatment
- Clinical trials of both drugs and medical devices
- BANN (Bayesian Artificial Neural Network) techniques for asset performance management and environmental monitoring and control

Current Status (4th Year)

During our last periodic report (period 3) we collected data from 30 patients in an observational study to test that the AVERT-IT technology meets the clinician's minimum requirements for sensitivity (>30%) and false positive rate (FPR) (< 10%) for prediction of arterial hypotension (low blood pressure). This work was successfully completed and the calculated sensitivity and specificity from using the BANN system in a live clinical environment were found to be 40.09% and 92.57% respectively. These encouraging results have allowed us to proceed to a Phase 2 study where we have completed the recruitment of the Phase II sequential clinical trial (D 6.3) which started in month 36 of last period and required recruiting 46 patients from six clinical centres (Glasgow, Uppsala, Barcelona, Monza, Heidelberg and Vilnius). We completed our recruitment target early and by the end of period 4 (month 42) had recruited 49 patients. The purpose of the Phase 2 clinical study was to assess whether or not a second cohort of patients would reproduce the research findings obtained during the Phase 1 study. The Phase 2 results indeed do produce similar results and therefore the two cohorts of patients were combined to provide a dataset of 69 patients. The results from this larger group of patients show that using the system, with false

positive suppression checks enabled and with a decision threshold of 0.4, yielded a sensitivity of 37.51% (95 C.I. bootstrap; 31.34 to 44.00) with a specificity of 91.2% (95 C.I. bootstrap; 88.70 to 93.48). These results will form the basis for a scientific paper to be published in a peer reviewed journal. A draft manuscript for this paper has been prepared and is included as D6.4 (report on Clinical Trial Results).

What does this mean for Avert-IT?

In simple terms, Avert-IT has taken major steps forward in patient diagnosis through the BANN development.

In the Avert-IT research to date, early assessment of the accuracy of the BANN to predict hypotension events is showing a very promising sensitivity for early identification of instability in arterial hypotension.

Future Work

Given our success to date, we are confident of meeting all of the scientific and technical objectives we have set ourselves within the Avert-IT project.

Consortium Members

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C3 Global Ltd
Uppsala Universitet
Universitätsklinikum Heidelberg
Azienda Ospedaliera San Gerardo Di Monza
Kauno Technologijos Universitetas
The University Of Glasgow
Greater Glasgow Health Board
Institut Català de la Salut
Philips Medizin Systeme Böblingen GmbH.

Further Information

For further information on the Avert-IT project, please visit the projects main web site at:

http://www.avert-it.org/

Contacts

For more information on the AVERT-IT project please contact the technical Manager Ian Piper (ian.piper@brainit.org) or the co-ordination Lydia Lepecuchel (lydia.lepecuchel@pera.com).
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