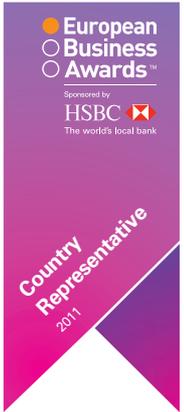


Case Study on:

FluidDA



Country Representative
European Business Awards 2011

Country Representative - Belgium
FluidDA nv

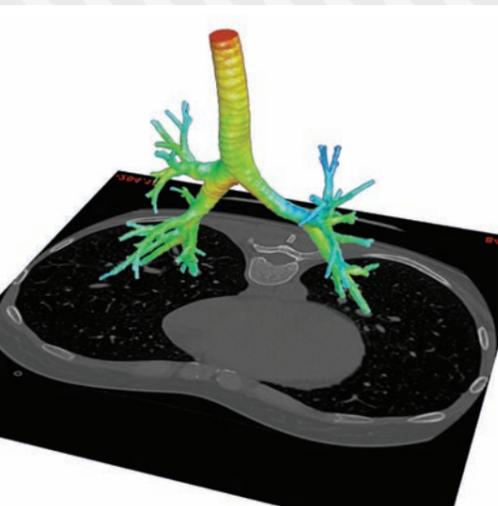
**European
Business
Awards™**

FluidDA

Introducing Pioneering Clinical and Technical Research Methods

Words from the Judges

“New treatment methods have potential to reduce number and cost of clinical trials.”



FluidDA is a clinical research organisation focusing on respiratory biomedical imaging. The company uses a combination of clinical imaging methods and advanced engineering tools to enhance the understanding of treatments targeted at improving the health of patients suffering from respiratory diseases. The company's main activities consist of developing imaging biomarkers to enhance drug development and improve patient care.

It is the company's innovative approach and pioneering research in the complex field of respiratory disease that have led the European Business Awards 2011 to select FluidDA as one of only 10 Country Representatives from Belgium.

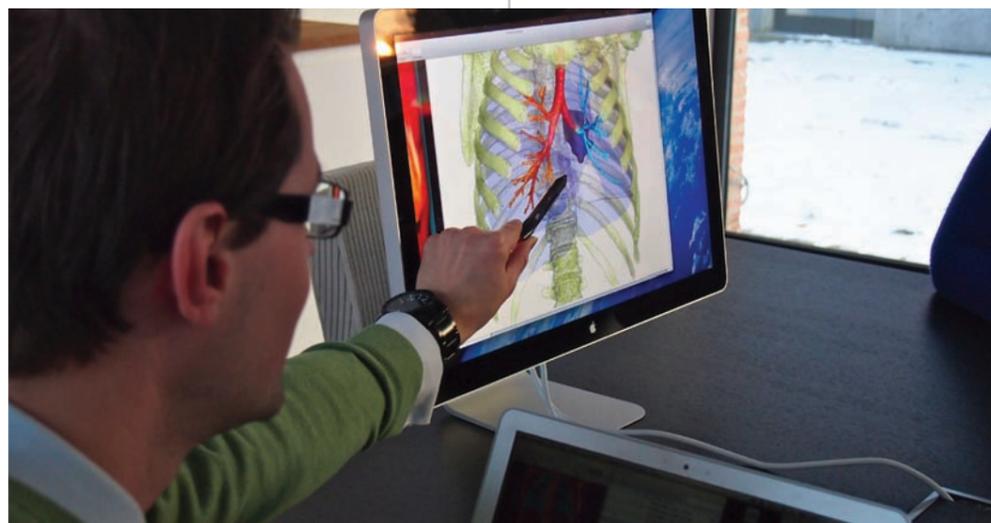
FluidDA was founded in 2005 to build upon the findings of a research project run through the University of Antwerp. The company aims to develop these findings further in the commercial world, with specific focus on innovative procedures. The company tests a patient's response to interventions including new inhalation medication, mechanical ventilation, stents and valves. The methods that FluidDA uses are more sensitive than other tests currently available and have the potential to considerably reduce the number of patients in clinical trials required to attain statistical significance.

“Our research method has the potential to not only reduce the development costs for new drugs or treatments but also the development time as significant results can be achieved by trialling less patients for a shorter time. In addition to use in clinical trials, clinical practices can also use the method to monitor and treat patients more effectively.”

Dr Jan De Backer, CEO, FluidDA

Respiratory products are extremely expensive to develop, costing the pharmaceutical industry many millions of dollars a year. The main reason for this high cost is attributed to the very low chance of obtaining regulatory approval for any new drug compound. FluidDA believes a lack of convincing evidence is a major reason of this inertia, caused in part by the low sensitivity of current clinical outcome parameters, which fail to describe clinically relevant changes in the respiratory system after treatment.

Country Representative



FluidDA has developed a method to describe changes in the respiratory system based on a combination of patient specific images, personalised computer models and flow simulations. The technique provides clinically accurate data that measures minuscule variations in airway volume and resistance as well as any number of other criteria.

“Our work uses a pioneering mix of biomedical imaging and aerospace engineering technology to successfully bridge the gap between the clinical and technical aspects of drug development.”

It is important that FluidDA builds a scientific base for its work. This includes the publication of manuscripts describing the benefits of the technique in key scientific journals in order to receive feedback from experts in the field. FluidDA has recently had several articles accepted by high-impact journals such as the European Respiratory Journal and Radiology, which have helped put the future of respiratory medicine firmly on the agenda for debate and discussion.

“The field of medicine is inherently conservative and often resistant to development. At FluidDA, we believe that someone needs to initiate the change through innovation and intensive research. The technique developed by FluidDA is showing positive, measurable and tangible results – we are now standing up and saying “this might be something”, take a look and see.”

The majority of the work taking place at FluidDA has been based on the results of a PhD thesis by current CEO, Dr Jan De Backer. Dr De Backer and the board of directors are all heavily involved in the company's activity. The company employs highly skilled people with a variety of backgrounds including engineers, medical doctors and biomedical scientists. The management further supports innovation by focusing on the development and protection of intellectual property. FluidDA has a number of patents and patents pending. As a young company FluidDA has made profits over the past three years which have been reinvested in R&D.

“FluidDA's success is built upon the innovative application of a combination of sophisticated biomedical imaging and advanced engineering tools to detect physiological or clinical changes in respiratory patients following an intervention. Their high sensitivity can reduce the number and cost of clinical trials required to bring an effective remedy to market. The result is year on year double digit growth in revenue and profit and creation of a unique space for FluidDA in this competitive market.”

Phil Forrest, Chairman of Judges, European Business Awards 2011



Looking to the Future...

FluidDA is entering a crucial phase in its history. The company has recently submitted data, results and other information on imaging biomarkers to the FDA (US Food & Drug Administration) and the EMA (European Medicines Agency) for approval. Additional studies are underway including a number of validation trials which are showing significant improvements in sensitivity when compared to the current spirometry lung function tests.

“Having approval from the FDA and EMA will give our findings the significant boost they need to be adopted on a larger scale.”

Using modern technology, FluidDA is able to operate a 'personalised medicine' approach using an individual combination of patient specific images, personalised computer models and flow simulations. A patient's results can be stored securely in the cloud so

they can be easily accessed by their personal physician, consultant and other clinical personnel who need to monitor treatment.

The company is looking to grow in the next few years, taking on more staff and expanding its operations. In 2011, the company opened a facility in Mumbai, India and employed new staff. The office in Belgium will now focus on high level analysis and further development of the methodology. The team in India will be responsible for processing and analysing all the data.

FluidDA is running trials at clinical centres in the Netherlands and Italy. This international, multi-centre testing is allowing FluidDA to disseminate information throughout Europe. The future aim is not only to implement FluidDA's methodology across a broader field of study but also to encourage centres across Europe to adopt FluidDA's technique.



“We are entering a new phase of our business. Being involved in a programme such as the European Business Awards helps give us credibility among the wider European community as well as with our own doctors, clinicians and patients.”



Jan De Backer, CEO, FluidDA

About FluidDA

FluidDA was founded in 2005 as a spin-off company from the University of Antwerp. FluidDA's main activities consist of developing imaging biomarkers to enhance drug development and patient care. The biomarkers combine biomedical imaging and advanced engineering methods to detect physiological or clinical changes in patients following an intervention. It has been demonstrated in recent studies that this original approach yields sensitive outcome parameters which provide additional insight into the mode of action of the intervention and allow for optimisation of the therapy.

To support the implementation of this novel method into clinical studies and clinical practice, FluidDA also offers a Contract Research Organisation (CRO) service with a specific focus on imaging research services. A complete package can therefore be offered to the client from initial protocol writing to full data analysis using the advanced processing techniques. To offer a high quality service FluidDA employs experts in all required fields from medical doctors to biomedical scientists and engineers.

About the European Business Awards

Since 2007, the European Business Awards programme has been shining a light on the most pioneering businesses on the continent by promoting excellence, best practice and innovation in the European business community. The awards programme recognises excellence in all disciplines of business including individual business functions. Last year entrants ranged from fish farming organisations to renewable energy firms. Together they had a combined turnover greater than €1 trillion Euros (8.23% of EU GDP) and employed over 2.7 million people between them.

Businesses from over 30 European territories entered the Awards. The competition for is fierce with many of the Europe's most established brands being represented. Entrants are judged by a panel of experts in their fields who bring experience, business acumen and understanding to the board.

Country Representatives are deemed by the judges to represent the very best companies in each territory. In 2011, the standard was particularly high, with the programme engaging with over 15,000 companies in the initial stages.

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