

## Who we are?

The ZCA-Braga is a Clinical Research Centre, located in the city of Braga, Portugal. It is a unique combination between the University of Minho (UM) and Hospital de Braga (HB), with a focus on research, clinical care, education and training. The ZCA-Braga is closely connected with the Life and Health Sciences Research Institute (ICVS-3Bs) and the School of Health Sciences (ECS) within the University of Minho. To strengthen and lead this non-profit partnership, considering the recognised capabilities in bioscience innovation and translational research of the several partners, the ZCA-Braga aims to promote with Hospital de Braga and Hospital CUF Porto the maintenance of health and, most importantly, contribute to add quality of life through innovative breakthroughs. The ZCA-Braga is now within three years of life and this Newsletter aims to provide some insight on the clinical research centre activities within this period along with additional actions planned for the future. We hope you enjoy the reading!

## Being a Principal Investigator at ZCA-Braga

The ZCA-Braga interviewed several Principal Investigators (PI) that are currently conducting clinical studies in this Clinical Research Centre:

**Professor Herlander Marques**, Hemato-Oncologist, who has been working in clinical trials since 1993 when he started to work at IPO Porto, **Professor João Cerqueira**, Neurologist who has been working in clinical trials since 2012 and **Dr. Jorge Marques**, Cardiologist Director, also working in clinical trials since 2014. They provided their views on how things have proceeded so far with their interaction with the ZCA-Braga, focusing on how the collaboration has been, what are the main success factors and where improvements can be made.



**“The collaboration has been excellent.** The location of the Hospital has allowed, the investigational team, to have a specific place to see research patients and work directly with the supporting clinical study team” mentioned Professor Herlander Marques, currently with 4 clinical trials on-going.



This view is also shared by other PIs, like Professor João Cerqueira, who is involved in 3 clinical trials and 4 observational studies, who also added that “The support of ZCA-Braga is excellent and essential to my role as clinical investigator. **The ZCA-Braga has an extremely efficient, dynamic team** who is always available to support us in all phases of a trial”.



The location, managing team and partnership of ZCA-Braga were highlighted as well by Dr. Jorge Marques, with 1 clinical trial and 2 observational studies currently active, at his department, mentioning that “the collaboration of the ZCA-Braga in clinical trials has been very important, **the location**

**of the Hospital building facilitates the contact between the investigators and study coordinators.** The managing team has facilitated the process leading to the study conduction”.

When inquired about the most important factors that contributes to the success in patient recruitment, the three PIs agree that having a dedicated professional Team to support in several administrative issues, patient management and follow-up has been the main reason for the recruitment success, aside from the location.

As Professor Herlander Marques mentioned “Having a dedicated and professional team providing administrative support has enabled me to focus on clinical aspects rather than administrative issues” where this has had a significant impact in the recruitment rates of his clinical studies. The location was also pointed out as an important point, by Professor João Cerqueira who mentioned that “the ZCA-Braga location within the Hospital and its connection with the Minho University, enables us to combine the feeling of being at home with the idea of research and innovation, in the same place, which captivates the patients”.

Dr. Jorge Marques also agrees that the support provided by the ZCA-Braga team is crucial through “the facilitation in the process of study execution and the support in the patient follow-up”.

There is still a path to be done, as improvements can always be made with the inputs provided by the interaction with the Clinical Investigational team, the Patients and the Clinical Research staff. So the PIs were also inquired on what could be improved. Professor João Cerqueira mentioned that “increasing the outreach effort, particularly directed at the resident population in the region” would be positive, as well as working on improving “the relationship with patient associations” and “other health institutions” which would provide opportunities for more patients to participate in cutting-edge research in a more structured way. Dr. Jorge Marques also suggested that the “involvement of various clinical departments, during the assessment phase of clinical studies, with at least one representative of each department for evaluation and allocation of studies to various departments” could also be an improvement. Professor Herlander Marques, stated that currently his opinion was that “the ZCA-Braga was working fine”.

Overall, the outcome is a positive one, as mentioned by Professor João Cerqueira “exceptional human resources and the location of the ZCA-Braga allows the patient to feel involved, but keeping a connection to “their Hospital”, promoting an easy interaction with all services and complementary exams without having to leave the building” and “the existence of a dedicated place and team makes life easier for investigators and patients, who make the visits more comfortably, contributing to an increased compliance and recruitment rate”.

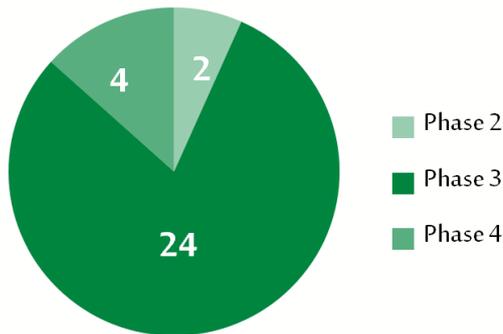
Our success lies in the close partnership with all of the stakeholders, from investigators, study nurses, technician, administrative staff to patients and Sponsor team, working closely to support each specific need toward the ultimate goal of contributing to the improvement of the patient’s quality of life.

## Our Figures

When compared to 2014, the current year has already seen an increase in the number of Studies that are initiated by the Investigator, also known as Investigator-Driven Studies (IDS) or Investigator Initiative Studies, as opposed to the Commercial Studies, which are defined as those who are sponsored by a Pharmaceutical or Biotech company. It is interesting to note that this increase is also associated to an augmented number of studies with Medical Devices (MDs), which is also a current trend observed in the field of Clinical Investigation, where new interventions using MDs are leading the way.

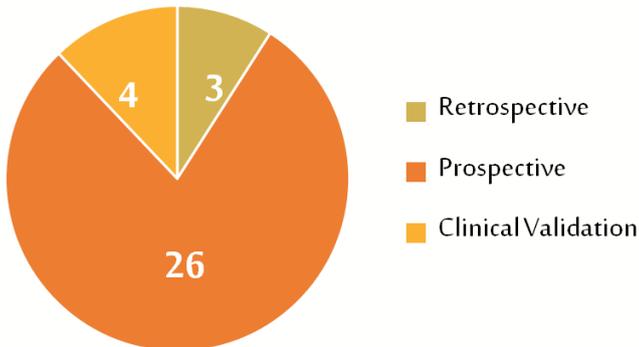
### Ongoing Studies - Total of 63 Studies

CLINICAL TRIALS N=30



Commercial Initiative N=28 | Investigator Initiative N=2

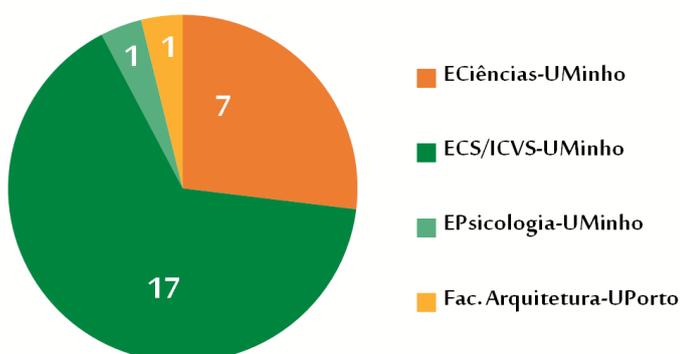
OBSERVATIONAL STUDIES N=33



Commercial Initiative N=9 | Investigator Initiative N=24

Of the 26 Investigator Driven Studies, the majority of them, 24, are Observational studies and these are across several distinct therapeutic fields, ranging from Stroke, Prenatal Development to studies with Orthopaedic Medical Devices. This is also a result from a very diverse Academic Collaboration fostered by the 2CA-Braga, which is depicted in the graph below.

ACADEMIC COLLABORATION



## Celebrating the 2CA-Braga Day

On March the 20th, it was celebrated the 2CA-Braga Day, dedicating a full morning to reviewing the past year achievement of 2CA-Braga. After the Opening Ceremony presided by Dr. João Ferreira, as Chairman of the Hospital's Executive Committee, Professor Nuno Sousa, from the Head of Clinical Research Unit of 2CA-Braga, presented an operational overview of 2CA-Braga's goals, activities, main achievements and the road ahead in terms of Clinical Research done at this Centre. The 2CA-Braga Grants for 2014 were awarded to the three winning projects and there was also the opportunity for the Awardees of the 2013 Grants, Professor Tiago Gil Oliveira and Professor João Cerqueira, to present the main developments of their projects. An important presentation on Biostatistics, in Clinical Research, by Professor Patrício Costa provided a much needed insight into some basic concepts. The 2CA-Braga Day concluded with an important protocol signature, celebrated between 2CA-Braga and InvestBraga, an economic agency of the municipality of Braga whose mission is to foster the economic development of the region and attract foreign investment. InvestBraga was represented by Carlos Oliveira, former Secretary of State for Entrepreneurship, Competitiveness and Innovation.



*The Grants 2014 winnings with Board of 2CA-Braga*

## What next?

The Clinical Research Training Course for the Study Nurse will be held on 13 to 17 July 2015. This week-long Course will cover two main topics: Clinical Research (Key concepts, Good Clinical Practices and Clinical Trial Implementation) and Biostatistics (using SPSS software). For more information on this course, please visit our website on [www.ccabraga.org](http://www.ccabraga.org).

On October 23<sup>rd</sup> the 2CA-Braga will be hosting the II Clinical Research & Innovation Journeys, an annual event which will continue to deliver important Clinical Research Workshops, targeting the Research Community of Investigators and Study Team members. This year, 2CA-Braga has invited key National Stakeholders in the implementation of clinical studies to contribute with their views on the current landscape of Clinical Research and Innovation. We are honoured to inform that the INFARMED (National Authority of Medicines and Health Products, IP), the CEIC (National Ethics Committee for Clinical Research) and the CNPD (National Data Protection Committee) have confirmed their presence in the event.

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