

Who we are?

The 2CA-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 2CA-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 2CA-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 2CA-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!

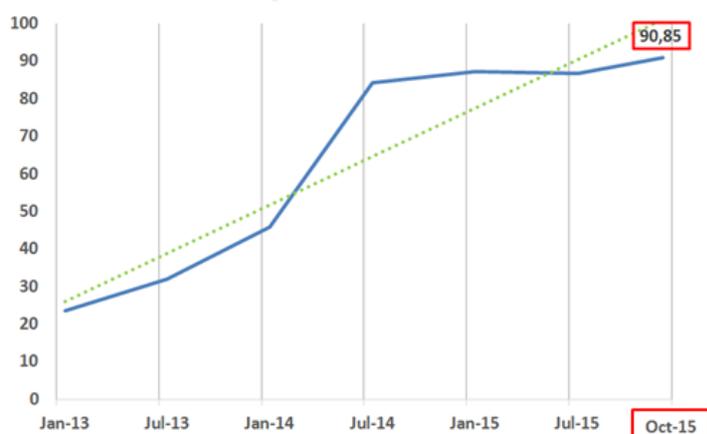
2CA-Braga Staff continues to grow

The 2CA-Braga is now within its three years of existence, registering a continuous increase in its staff numbers. Researchers, the Clinical Research Unit team, the Ancillary Services and the Scientific Board, all of them have been key in the success of its implementation.

The Clinical Research team has been reinforced by two additional Study Coordinators and one Study Nurse, comprising now one Project Manager, one Financial Coordinator, one Study Assistant, three Study Coordinators, two Study Nurses and the Head of the Clinical Research Unit. The staff is supported by a Scientific Board and by Ancillary Services (such as Pharmacy, Radiology, Pathology Lab and Nuclear Medicine), as well a group of Researchers, which are currently around 160 amongst *Hospital de Braga* and the Life and Health Sciences Research Institute - ICVS. All the fundamental elements are present to potentiate the accomplishment of important clinical research achievements at 2CA-Braga.

90% Patient Recruitment rate

Our Recruitment rates have been steadily improving over time as depicted in the figure below, exceeding 90% in October 2015. In fact, since July 2014, our recruitment rates have been above 85%. This clearly shows the ongoing commitment of the 2CA-Braga with its mission. Successful patient engagement and recruitment is crucial when working in clinical research. Being able to ensure that recruitment efforts are met is a shared goal between Sponsors and the 2CA-Braga team.



Clinical Research Training Programme at 2CA-Braga

Between the 9th and 13th of November 2015, the 2CA-Braga will host the 3rd Edition of the Clinical Research Training Programme, targeting Physicians, Nurses and Pharmacists, as well as Researchers and other Professionals who are engaged in Clinical Research.

In its mission statement, the 2CA-Braga has a clear focus on education and training in the Clinical Research field, for which this specific Programme has been developed. Covering important topics, such as: Introduction to Clinical Research, Regulatory framework, Good Clinical Practice (GCP), Clinical Protocol Development, Clinical Study Submission and Statistical Analysis (using SPSS), two Editions have been successfully completed this year.



We share below some of the comments of the students that participated in the Programme regarding what they found to be best in each training course:

1st Edition (March 2015) – Internal Medicine Residents:

"The objective, targeted and simplified way the contents were presented"

"Practical transmission of knowledge"

"Systematic and clear approach to the concepts"

2nd Edition (July 2015) – Nurses:

"I hope that in the future we can develop together clinical research projects"

"The course was undoubtedly a great help for us to develop the Research on Nursing in the Hospital de Braga and CUF Academy"

"Congratulations on the Programme! It was really worth it!"

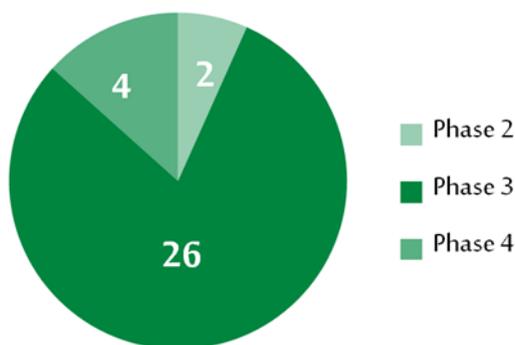
"Good practical applicability of the concepts"

An Update on Ongoing Studies

An impressive number of 69 ongoing studies are now running in the 2CA-Braga. 41 studies consist of Commercial Studies (defined as those who are sponsored by a Pharmaceutical or Biotech company) and the remaining 28 are Clinical Projects that were initiated by the Investigator, also known as Investigator-Driven Studies (IDS).

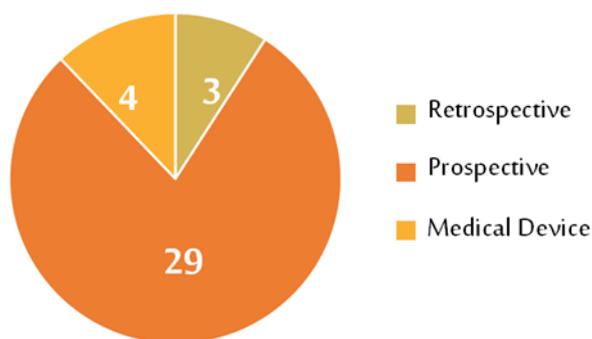
ONGOING STUDIES - 69

CLINICAL TRIALS N= 33



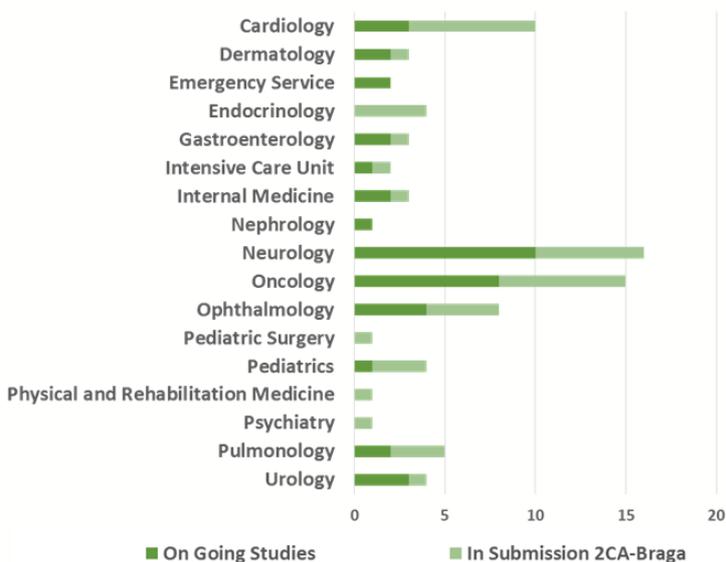
Commercial Initiative N=32 | Investigator Initiative N=1

OTHER CLINICAL STUDIES N= 36



Commercial Initiative N= 9 | Investigator Initiative N=27

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.



Coming Soon: Phase I Unit at 2CA-Braga



In January 2016, the 2CA-Braga expects to be launching the Phase I Unit and early stage studies, benefiting from the consolidated experience and achievements in what concerns later stages of the clinical research.

With a fully-dedicated facility within the Hospital de Braga, the Phase I Unit is currently under preparation, both at the level of infra-structures, as well as the regulatory compliance regarding the healthy patient database approval requested to the CNPD (National Data Protection Committee). Additionally, the 2CA-Braga is currently involved in the feasibility process regarding three Phase I studies, which demonstrates reliance from Sponsors in 2CA-Braga.

What next?

On October 23rd, the 2CA-Braga will be hosting the II Clinical Research & Innovation Journey, an annual event which provides 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. The 2CA-Braga is very pleased to count with the participation of INFARMED (National Authority of Medicines and Health Products, IP), CEIC (National Ethics Committee for Clinical Research) and CNPD (National Data Protection Committee) in this important event.

For more information <http://www.ccabraga.org> or contact us through 2ca@ccabraga.org.



Contacts 2CA-Braga

Email: 2ca@ccabraga.org

Phone: +351 253 027 249

Mobile Phone: +351 915 303 511

<http://www.ccabraga.org>

Hospital de Braga, Lugar de Sete Fontes, S. Victor

4710-243 Braga, Portugal