Clinical research as a tool to seize value

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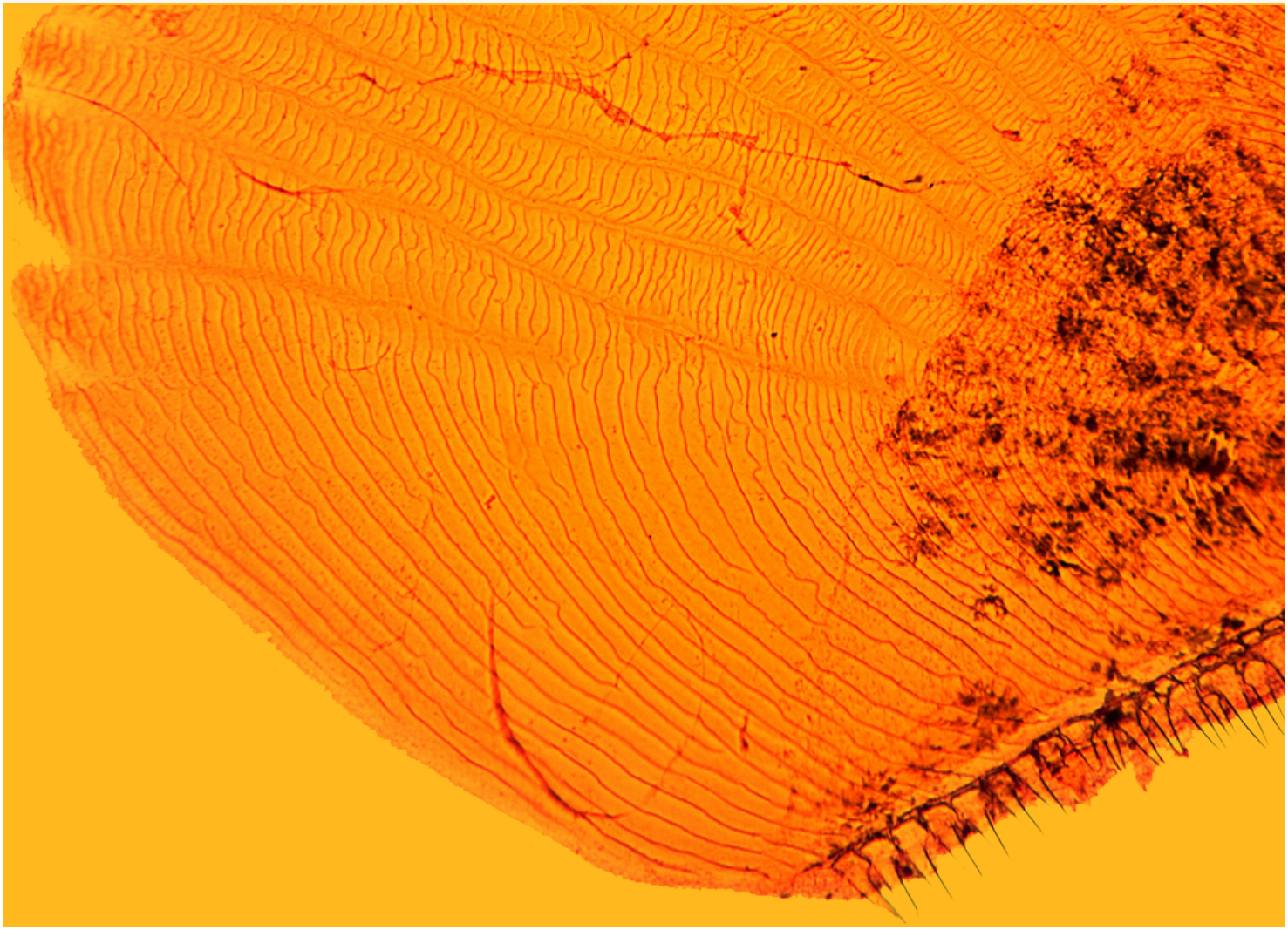

The universal challenge facing all modern healthcare systems is to reach a high overall level of health with an accessible, integrated, quality care model that is also sustainable. This means healthcare systems must be made more efficient, freeing up available resources to allow people to live longer, healthier lives.

In Catalonia, this task of freeing up resources comes up against the fact that the demand for healthcare is increasing due to the ageing population and an increasingly complex morbidity profile. On one hand, life expectancy is nearly two years above the European average (1.9 years above the EU-15) and, on the other, the number of patients with chronic illnesses (heart failure, obstructive pulmonary disease, diabetes, mental disorders, depression, dementia and cancer) and associated comorbidities is rapidly growing and putting increasing pressure on the healthcare system, which already has financial problems and overworked healthcare professionals.

Faced with this situation, which is the same to some extent in all developed countries, Catalonia must seek out new healthcare, economic, social and technological paradigms to address these needs. Efficiency can be boosted incrementally by rationalizing prescriptions, promoting good healthcare practices, educating patients on consumption, speeding up the administrative processes and cutting down on fraud, but this isn't enough. A wholesale transformation of the healthcare system is needed. And it may be necessary to transform hospitals into integrated service units where patients can receive comprehensive care, as Michael E. Porter and Thomas H. Lee propose in their article

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The Strategy That Will Fix Healthcare, (HBR, October 2013). These authors argue that the only way to boost value for patients is to achieve "desired health results" at a lower cost, and that means structuring healthcare around patient needs, which is a "whole" and not a "series of different conditions" that different specialists deal with from independents departments. These authors also insinuate that payment for healthcare should be based on what the patient gets out of it, not volume. This implies using powerful IT systems that can handle all life and health information at once, and also having tools to measure the individual cost of care for each person.

Although Catalonia, unlike other countries, has not yet begun the shift from public hospitals towards integrated service units (like, for example, Norway at the new Oslo University Hospital), it has begun down the path towards the sustainability and progress of the healthcare

system by reinforcing protection and promotion of health, disease prevention, food safety and clinical research.

Promoting research is in line with one of the main messages of the World Health Report (WHO 2013), which says all countries must both produce and consume research. Beyond investing in new technology, the report says we must invest in making better use of existing knowledge. This means transforming it into practical applications that address real health problems. The WHO proposes increasing collaboration between governments, universities, research centers, international organizations, hospitals and private companies in order to bridge the gap between these different parties.

To take the path the WHO recommends, in Catalonia we must move towards integrating clinical research into medical practice, which will lead us to redefine the role of healthcare professionals, pharmacists, academic researchers, patients, family members and caregivers. Likewise, to move towards personalizing treatment as a service, more than as a product, as Porter and Lee recommend, in Catalonia we must push forward in recognizing the complementarities of the public healthcare system and private initiatives.

This article covers current trends in clinical research, the reach of clinical trials in hospital centers in Barcelona and the initiatives of the Government of Catalonia Department of Health to promote transversal actions that make clinical research in Catalonia more efficient and have a greater impact. In particular, it will discuss the creation of the Barcelona Clinical Trials Platform (BCTP), an instrument to attract more clinical research to Catalonia with the aim of seizing value for patients and the healthcare system itself.

Current trends in clinical research

The pressure to do trials quickly and efficiently has increased exponentially over the past ten years. It could be said that this increase has been proportional to society's recognition of the value trials contribute in terms of health and wellbeing, to patients' expectations of making fatal diseases into chronic conditions, and to companies' desire to make the most of drugs before patents expire.

The Barcelona Clinical Trials Platform is an instrument to attract more clinical research to Catalonia with the aim of seizing value for patients and the healthcare system itself

In recent years, despite the slowness of the main regulatory agencies (the United States Food and Drug Administration and the European Medicines Agency) in incorporating technological advances into clinical trials, there have been interesting changes like decreased use of printed paper for collecting data and a move towards electronic trials, even electronic storage of clinical trial archives, which is a great savings logistically, reducing the space required and improving access without sacrificing security. Progress has also been made in moving towards electronic signatures, although there isn't yet a universally accepted, fully compatible solution that both pharmaceutical laboratories and hospital researchers can adopt.

Information and communication technology (ICT) has evolved so quickly, and has such potential when applied to clinical research, that current debate focuses on how to boost ICT to make the development of therapeutic molecules and medical devices faster and cheaper.

Real-time data capture in clinical trials improves transparency (as does registering and publishing all clinical trials). At the same time, this also makes it possible to decentralize trials, which means studies can be done far from the hospital, expanding the sphere of recruitment and making patients more comfortable and more likely to adhere to treatment.

ICT also allows clinical trial data to be integrated with real-world data, not only regarding health but also socioeconomic aspects, etc., and to build a joint system of big data that, once integrated and analyzed, makes it possible to take strategic decisions at the right time. These decisions may be to continue developing a molecule or be epidemiological in nature.

Social networks make it easier for patients to participate in the drug-development process and are a tool to maintain patient centricity.

In addition to the contributions of ICT, there have been other scientific evolutions applied to medicine that have enriched the debate on how to make clinical development more efficient. Three good examples are precision medicine, adaptive design and collaborative initiatives:

- Precision medicine means each patient can be assigned the most appropriate treatment at the right dose, making clinical trials faster and with fewer participants (example 1: ASCO's Targeted Agent and Profiling Utilization Registry- TAPUR study; example 2: the National Cancer Institute – MATCH study: Molecular Analysis for Therapy Choice trial).

- Adaptive design, which tests multiple hypotheses in the same study and allows the design to change over the course of the study, based on the results, also allows doctors to move patients from one branch of a trial with an ineffective treatment to one in which the treatment works (for example, European Prevention of Alzheimer's Dementia -EPAD project).

- Collaborative initiatives from consortia of companies, governments, regulatory bodies, preclinical and post-clinical researchers, patients' associations, etc., that create open repositories of data and share methodology, structures, standards and training to benefit the whole community (for example, Transcelerate).

With all of these changes to how clinical trials are designed (adaptive protocols), how data is collected (real time), how it is integrated and analyzed (big data) and how trials are funded (public-private partnerships), we are living in a time of great changes in the world of clinical research. Two books that discuss this are *The Guide to the Future of Medicine: Technology and the Human Touch*, by Bertalan Meskó, and *The Patient Will See You Now*, by Eric Topol.

We are moving from paying service providers (like CROs) to working to make them partners in the process and compensating them for the value received. A transition is underway from "one-size-fits-all" studies to studies based on "precision medicine" (more adapted to the target population) and from mainframe clinical trials (those conducted right around the hospital) to hand-held clinical trials (remote studies) thanks to mobile apps and home devices like smart clothing (for example, Hexoskin) and digitals tattoos (for example, Someya Organic Transistor Lab) that control patient health, diet, activity, etc. These advances continuously monitor patients, replacing sporadic medical care (doctors visits) with ongoing patient care.

Barcelona Clinical Trials Platform

With the aim of positioning Catalonia among the leading European regions in conducting clinical trials, Barcelona Clinical Trials Platform (BCTP) brings together the most important institutes in Catalonia by volume of clinical trials into a single platform to improve the coordination, integration, quality, inclusivity and speed of clinical research.

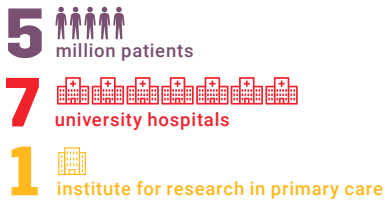
BCTP was created by the Department of Health and Biocat in the final quarter of 2014 to position Catalonia among the top five European regions for conducting clinical trials

BCTP was created by the Department of Health and Biocat in the final quarter of 2014. The strategic line of the Catalonia Health Plan 2016-2020 dealing with research and innovation promotes the consolidation of the BCTP with the aim of increasing the number, quality and importance of clinical trials conducted in Catalonia. By having different centers join forces and take advantage of synergies in clinical research, it will be possible to attract innovative therapies in the early stages of development to Catalonia.

As of January 2015, the centers that belong to the platform totaled 2,740 participations in trials, with 13,498 patients recruited. BCTP kicked off as a pilot program but it is expected to expand in the middle term to include other research institutes and hospitals in Catalonia. This initiative is inclusive and provides a joint structure covering the whole region so that hospitals in Catalonia may act as a sort of metacenter that is a benchmark in developing new drugs, medical devices and biological products.

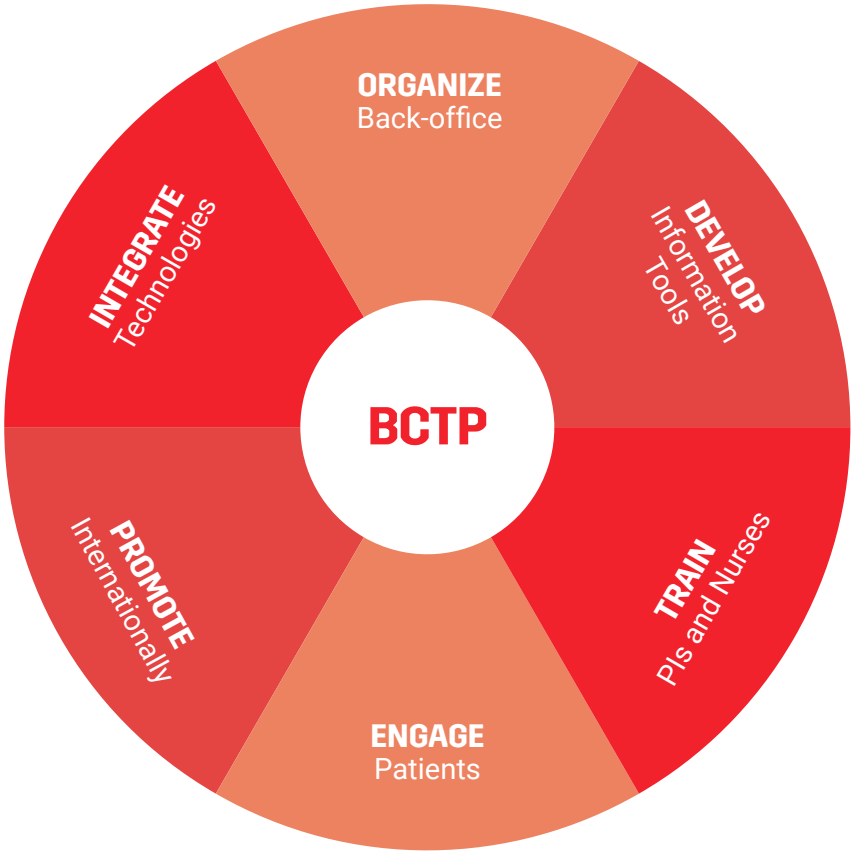
The greatest challenge facing the founding members of the BCTP is to align patients' needs with researchers' expertise and industry's aims in order to speed up the arrival of innovative treatments and improve the results of public health policies and interventions.

BCTP is a gateway for clinical trials, with access to 5 million patients.



Source: BCTP

BCTP areas of action to achieve collective excellence in clinical trials in order to attract and develop innovative treatments in Catalonia.



1. Simplified bureaucracy to cut negotiation and authorization times for clinical trials and facilitate the transfer of patients between centers to give patients access to therapies being developed.

2. Centralized information to enable integrated, cohesive, efficient running of its member institutes by creating collaborative computer tools.

3. Lifelong learning for clinical trial staff to ensure researchers and nurses are trained, certified and up-to-date with best clinical practices (BCP).

4. Commitment to patients to make the general public more aware of clinical trials and inform potential patients of the trials conducted in Catalonia.

5. Joint promotion of members to boost the collective international visibility of the member institutes at fairs, congresses and events in the sector.

6. Integrating research into clinical practice to channel the research expertise and technology present in Catalonia towards clinical development of targeted therapies and a move towards personalized healthcare.

Source: BCTP

Metrics for clinical research in Catalonia

The BCTP's main asset is its concentration of key opinion leaders with significant scientific leadership in many therapeutic areas, who can provide insight into the impact and feasibility of emerging therapies, participate in designing clinical trials and analyze results. Nevertheless, collective excellence in clinical trials must be measured with specific indicators aligned with the industry's interests (metrics: volume of studies initiated, time to regulatory authorization, length of contract negotiations, recruitment index, etc.) and these metrics must be measured in the same way at all institutes.

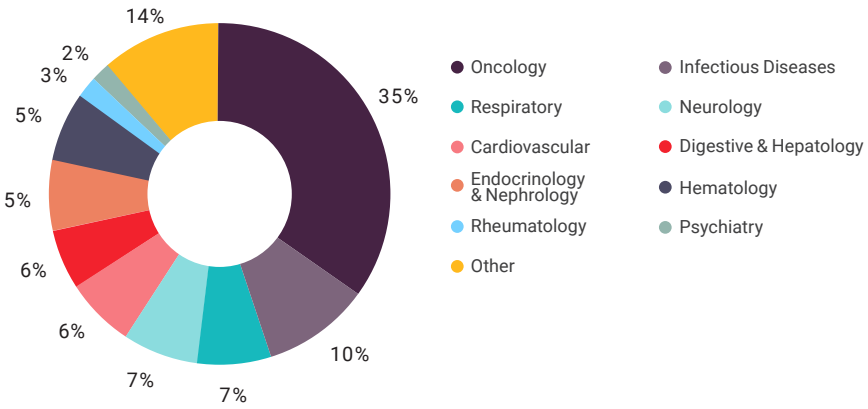
The BCTP has retrospectively collected metrics for the 2012-2014 period from each of the member institutes. So, the current benchmarks for the BCTP come from compiling the clinical trials conducted individually by each member. With the bureaucratic simplification implemented by the BCTP and the integration of clinical trials and medical practice, more studies will be attracted to the region and, presumably, there will be a positive evolution of these base metrics, which appear below.

Newly initiated clinical trials (2012 - 2014)

2,515
sites participating in clinical trials initiated between 2012 and 2014

78%
participations in pre-registration phases (Phases I, II and III)

New clinical trials (2012-2014) by therapeutic areas:

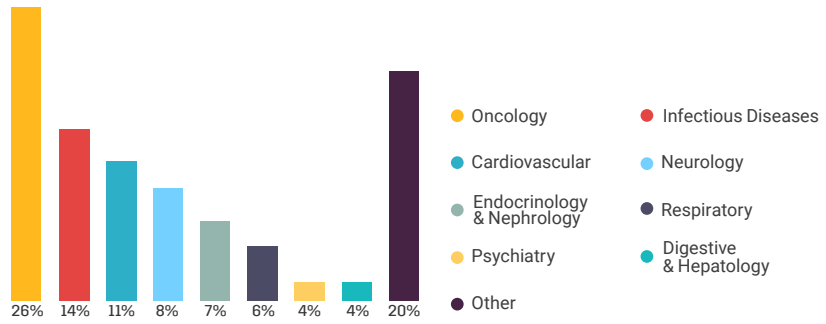


Completed clinical trials (2012-2014)

1,487
sites participating in clinical trials completed between 2012 and 2014

13,287
patients recruited

Patients recruited into completed clinical trials (2012-2014) by therapeutic area:

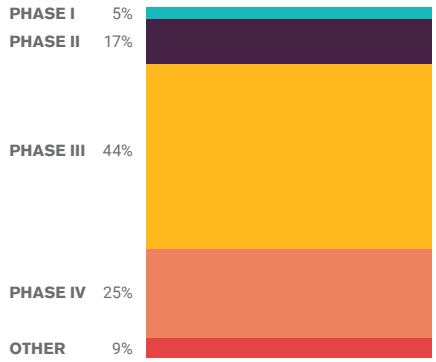


Ongoing clinical trials (as of January 2015)

2,740
sites participating in ongoing clinical trials

13,498
patients recruited

Patients recruited into ongoing clinical trials by phase:



Oncology

Completed trials (2012-2014):

467 Sites participating

3,503 Patients recruited

Ongoing trials as of January 2015:

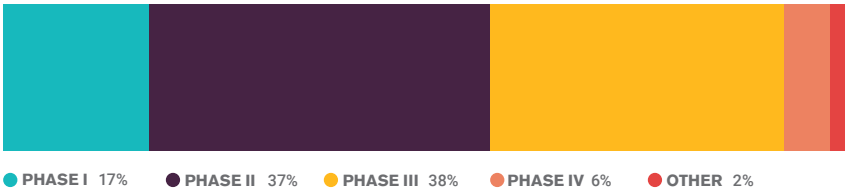
935 Sites participating

3,635 Patients recruited

Source: BCTP

Newly initiated trials (2012-2014):
(% of sites participating by phase)

TOTAL 886 centers



Infectious Diseases

Completed trials (2012-2014):

151 Sites participating

1,864 Patients recruited

Ongoing trials as of January 2015:

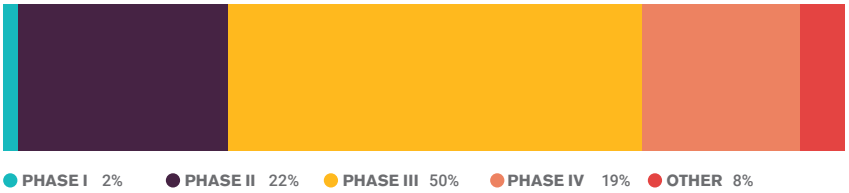
277 Sites participating

1,533 Patients recruited

Source: BCTP

Newly initiated trials (2012-2014):
(% of sites participating by phase)

TOTAL 245 centers



Digestive & Hepatology

Completed trials (2012-2014):

102 Sites participating

452 Patients recruited

Ongoing trials as of January 2015:

138 Sites participating

572 Patients recruited

Source: BCTP

Newly initiated trials (2012-2014):
(% of sites participating by phase)

TOTAL 140 centers

Respiratory

Completed trials (2012-2014):

110 Sites participating

815 Patients recruited

Ongoing trials as of January 2015:

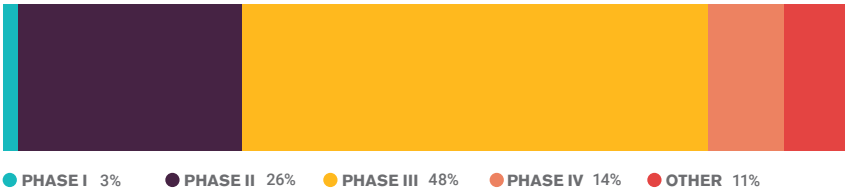
130 Sites participating

556 Patients recruited

Source: BCTP

Newly initiated trials (2012-2014):
(% of sites participating by phase)

TOTAL 189 centers



Cardiovascular

Completed trials (2012-2014):

95 Sites participating

1,452 Patients recruited

Ongoing trials as of January 2015:

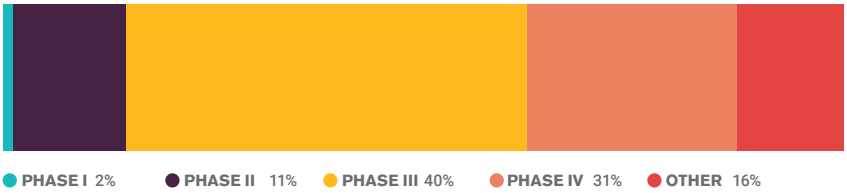
226 Sites participating

2,325 Patients recruited

Source: BCTP

Newly initiated trials (2012-2014):
(% of sites participating by phase)

TOTAL 156 centers



Neurology

Completed trials (2012-2014):

147 Sites participating

1,023 Patients recruited

Ongoing trials as of January 2015:

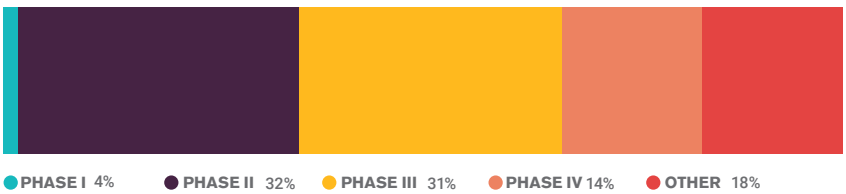
241 Sites participating

867 Patients recruited

Source: BCTP

Newly initiated trials (2012-2014):
(% of sites participating by phase)

TOTAL 185 centers



Endocrinology & Nephrology

Completed trials (2012-2014):

85
Sites participating

953
Patients recruited

Ongoing trials as of January 2015:

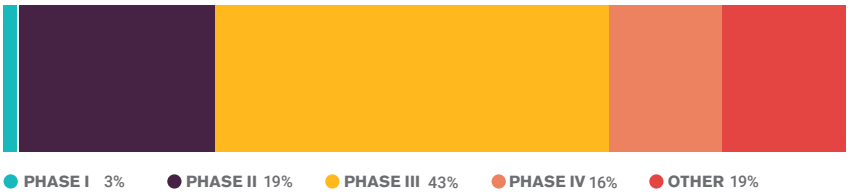
167
Sites participating

1,247
Patients recruited

Source: BCTP

Newly initiated trials (2012-2014):
(% of sites participating by phase)

TOTAL 121 centers



Like what is happening in other developed countries, Catalonia is preparing to address the challenge of growing demand for healthcare on a large scale with unique characteristics, which include ageing and chronic diseases with associated comorbidities. Diagnostic, therapeutic and technological advances, as well as transforming hospitals into integrated service units for patients, are the way to tackle this challenge, as is integrating clinical research into medical practice.

In this context, it makes sense that the Department of Health and Biocat decided to create a clinical trials platform (BCTP) to forge new pathways for collaboration between hospitals and pharmaceutical companies, contract research organizations (CRO), governmental agencies and medical societies to attract large clinical trials to Catalonia. If all hospitals work within the platform, we will create a critical mass, foster repetition of opportunities and cross-pollination between similar programs.

Finally, the efforts of the BCTP to integrate clinical research into medical practice will allow us to offer patients innovative treatments. Through clinical research we bring the talent and technology from Catalonia's research institutes and hospitals to the patients, thus seizing the value we generate through research.

With the bureaucratic simplification implemented by the BCTP and the integration of clinical trials and medical practice, more studies will be attracted to the region