



Barcelona Clinical
Coordinating Center

Science that moves lives forward

We bridge the gap between bold medical ideas and real-world impact, advancing clinical research with precision and purpose.

Capabilities deck



About us

Barcelona Clinical Coordinating Center (BCCC) is a European **non-profit CRO** (Contract Research Organization) supporting startups, biotech, medtech & pharmaceutical companies with end-to-end clinical trial execution, post-authorization studies, and expert consulting in regulatory affairs, statistics, and centralized image analysis.



Based in Barcelona, Spain



Non-profit organization



European expertise with international mindset



BCCC office

What working with a non-profit CRO means

BCCC is a brand of Món Clínic, a **non-profit** private foundation whose mission is to protect health and strengthen people's health to help improving the quality of life of all citizens and promoting the progress of health professionals.



Fair & transparent pricing

Costs reflect real work, not profit maximization.



Profit with purpose

Any surplus is reinvested to improve healthcare, research & patient outcomes.



Mission-driven CRO

No investors or shareholders. Decisions are guided by patient health, scientific and regulatory value.





Challenges We Help You Solve at BCCG

From development to market access — end to end

- Navigating complex clinical trials in Europe & Spain
- Managing regulatory hurdles and tight timelines
- Identifying sites and recruiting the right patients
- Operating with limited internal resources
- Needing strong local expertise with global reach

How we help

- Practical, hands-on CRO experience
- Deep regulatory and scientific know-how
- Streamlined support from design to approval and beyond



Leadership that sponsors trust



Jordi Carrión
CEO

- CEO of Món Clínic Foundation (FMCB), which houses BCCC.
- Executive with extensive experience in business leadership, entrepreneurial growth, and organizational strategy



Xavier Luria
Executive Director

- Deep expertise in regulatory strategy and benefit–risk
- Highly experienced drug and medical device development expert
- Former CEO at DDR, later acquired by Veristat
- Former Head Safety & Efficacy of Medicines at EMA



Josep Rodés-Cabau
CSO

- A globally recognized clinical researcher and cardiologist with 25+ years of experience.
- Works at the Quebec Heart & Lung Institute — the largest cardiology centre in Canada
- Former Director of Research & Innovation at Hospital Clínic Barcelona.



Isabelle Bazso
Director Operations

- Brings 25+ years of industry and CRO experience, including roles in clinical operations, quality assurance, and oversight.
- Enabling teams to deliver compliant, high-quality operational results for clients.



Laura Oleaga
Core Lab Director

- Radiologist specializing in neuroradiology, with a particular focus on head and neck and brain tumors.
- Actively involved in European radiology education, supporting high standards in European radiology training and certification.

Our therapeutic & study experience

Therapeutic areas:

Cardiology

Dermatology

Gastroenterology

Urology

Oncology

Hepatology

Infectious dis.

Musculoskeletal

Women's health

Pneumology

Nephrology

Neurology

Neurovascular

Mutidisciplinary

Rare diseases

Modalities:

Drugs

Advanced
therapies

Medical devices

Diagnostics

Combination
products

Study phases:

Feasibility
studies

Pilot studies

Phase I

Phase II

Phase III

Post-
authorisation

Real World
Evidence (RWE)





Our services

We offer comprehensive services, from site selection to statistical analysis and study reporting, fully under the GCP international regulations.

Clinical development



Our clinical research experts guide your study through every phase, ensuring scientific rigor, efficient processes, and compliance with international regulatory requirements.

Regulatory consulting



Our regulatory experts provide support through every phase of the product life cycle, whether you are developing a drug, a medical device, diagnostics, or a combination product.

Statistical consulting



We provide tailored statistical consulting that blends deep methodological expertise with hands-on support, guiding from early study design to final data interpretation and publication.

Image core lab



We provide centralized imaging analysis capabilities that deliver consistent, precise, and reliable image interpretation, integrated into your research workflows, in collaboration with Eco Core Lab of Quebec.



Our services



**Clinical
development**



**Regulatory
consulting**



**Statistical
consulting**



**Image core
lab**

1

Trial planning & feasibility

We assess feasibility, risks, timelines, and operational trial requirements.

2

Study start-up

We manage site activation, approvals, contracts, and study initiation.

3

Study management & oversight

We provide end-to-end operational leadership and trial oversight.

4

Site management & monitoring

We ensure site performance, compliance, and high-quality data execution.

5

Patient recruitment & retention

We support enrollment strategies to optimize recruitment and retention.

6

Quality & compliance

We ensure ICH-GCP compliance and inspection-ready trial conduct.

7

Study close-out & transition

We manage efficient study close-out and smooth trial transitions.



Our services



**Clinical
development**



**Regulatory
consulting**



**Statistical
consulting**



**Image core
lab**

1

Trial planning & feasibility

- Operational feasibility assessment
- Country and site feasibility
- Timeline and milestone planning
- Risk assessment and mitigation planning
- Operational input to protocol design

2

Study start-up

- Site identification and selection
- Regulatory submission coordination
- Site contracts and budget negotiation
- Site initiation and training
- Site activation and readiness

3

Study management & oversight

- Overall study management & leadership
- Study plans, timelines, and tracking
- KPI monitoring and reporting
- Cross-functional coordination
- Budget and financial oversight

Our services



**Clinical
development**



**Regulatory
consulting**



**Statistical
consulting**



**Image core
lab**

4

Site management & monitoring

- Monitoring strategy (on-site & remote)
- Site performance & compliance oversight
- Data review and query follow-up
- Protocol deviation management
- Ongoing site support & issue resolution

5

Patient recruitment & retention

- Recruitment strategy and planning
- Enrollment tracking and forecasting
- Site-level recruitment support
- Patient retention planning
- Recruitment risk mitigation





Our services



**Clinical
development**



**Regulatory
consulting**



**Statistical
consulting**



**Image core
lab**



6

Quality & compliance

- ICH-GCP compliance oversight
- TMF management & quality control
- Audit and inspection readiness
- CAPA management and follow-up
- SOP implementation and adherence

7

Study close-out & transition

- Site close-out and documentation
- IP reconciliation & site payments
- Vendor close-out
- TMF finalization and archiving
- Study transition or handover support



Our services



Clinical
development



**Regulatory
consulting**



Statistical
consulting



Image core
lab

→ Strategic regulatory advice

Tailored guidance for medicinal products, medical devices, diagnostics, and combination products in Europe, UK, and US.

→ Product categorization & classification

Product regulatory categorisation and classification to guarantee that the development program aligns with the regulatory framework.

→ Health authority interactions

Support in preparing for and managing procedures with EMA, MHRA, FDA and national agencies through the whole product lifecycle.

→ Regulatory training

Workshops and training sessions to build internal capacity in companies and institutions.





Our services



Clinical
development



Regulatory
consulting



**Statistical
consulting**



Image core
lab

→ **Statistical methods & modeling**

Selection and implementation of appropriate techniques tailored to your study goals.

→ **Sample/study size estimation**

Reliable calculations to ensure adequate power and feasibility.

→ **Regulatory documentation & agency support**

Preparation of statistical sections for product dossiers and support during interactions with regulatory bodies.

→ **Clinical trial & epidemiological study design**

Expert input for interventional and non-interventional research, including protocol development and statistical analysis plans (SAPs).

→ **Scientific communication**

Assistance in interpreting, presenting, and publishing results, including graphical visualizations and manuscript contributions.



Our services



Clinical
development



Regulatory
consulting



Statistical
consulting



Image core
lab

We can centralize the analysis of several type of images:

CT scan

MRI

X-ray

PET

...

Our expertise spans across these therapeutic areas:

Cardiology

Neurology

Musculoskeletal

Oncology

...

→ Centralized image analysis

Robust and reproducible imaging assessments ensuring accuracy and consistency.

→ Seamless database integration

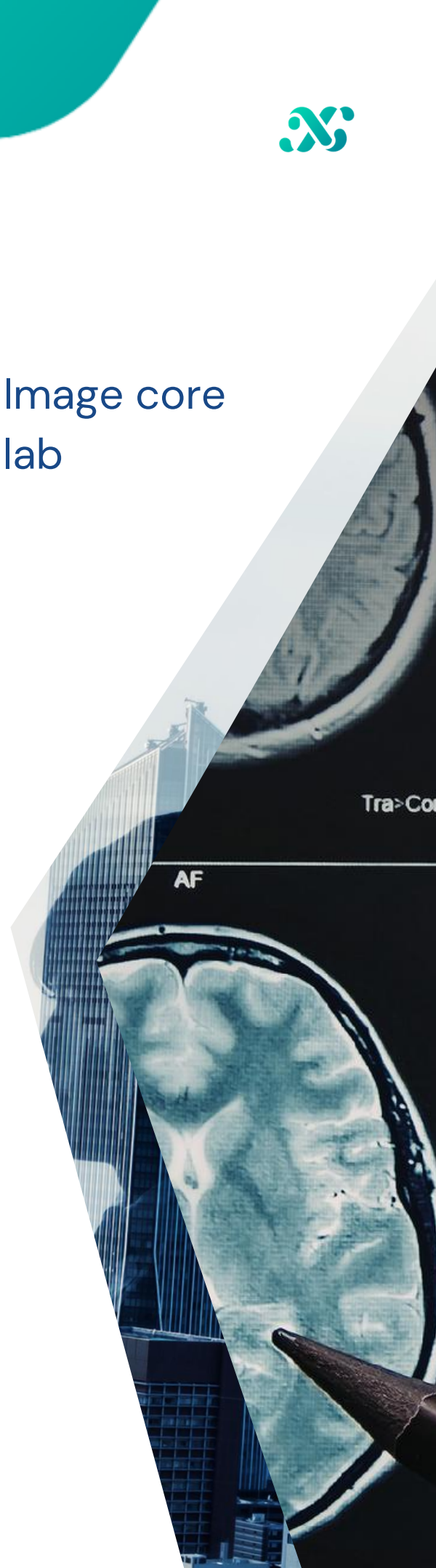
Smooth integration of imaging data into your existing research platforms.

→ Customizable reporting

Tailored reports that align precisely with your research objectives and regulatory needs.

→ Guided protocols

Standardized imaging procedures that reduce variability and enhance data reproducibility.





Services we offer in collaboration with Hospital Clínic of Barcelona



HTA

(Health Technology Assessment)



Accelerate European market access and reduce risk through integrated HTA strategy.

By embedding HTA into your portfolio from the outset, you prioritize the “added value” evidence required to move beyond CE marking or marketing authorization to secure reimbursement in competitive global markets.



HTA: De-risking with Early HTA

Services we offer in collaboration with Hospital Clínic of Barcelona

Conducting HTA before the CE mark reduces risk and aligns development with payer needs.

Strategic Advances:

- Shapes design and evidence-generation strategy.
- Identifies evidence gaps before major investment.
- Informs critical Go/No-Go development decisions.
- Serves as a valorization tool for investor readiness.



HTA: Market Access Beyond the CE Mark

Services we offer in collaboration with Hospital Clínic of Barcelona

Under the new European HTA Regulation (2021/2282), regulatory approval is just the beginning.

To secure reimbursement, technologies must demonstrate clear **added value**:

Evidence for payers: Framing assessments to meet the specific requirements of healthcare systems.

Value Drivers: Identifying clinical, economic, and organizational impacts early.

Real-World Settings: Generating evidence that strengthens the case for system uptake.

Barrier Mitigation: Proactively identifying and addressing potential hurdles to adoption.

Case study

iVascular

ANGIODAPT-01 is a randomized controlled clinical trial sponsored by iVascular to evaluate an abbreviated dual antiplatelet therapy (DAPT) regimen following drug-eluting stent implantation.

Study Objective

The study assesses whether a 1-month DAPT strategy can provide comparable clinical protection to the standard 6–12-month regimen. It compares the performance of the iVascular's Angiolite coronary stent with another commercially available stent to determine the safety and efficacy of an abbreviated antiplatelet approach after percutaneous coronary intervention.

BCCC provided:

- End-to-end trial management
- Oversight of external committees and key stakeholders (TSC, CEC, DSMB)
- Robust and reliable evidence on stent performance and DAPT strategies

3

Countries

39

Sites

2,132

Patients



Why work with a CRO like BCCC

- Non-profit organization
- Strong medical support
- Personalized service
- Faster decision-making
- Flexibility & tailored solutions
- Long-term partnership mindset





Thank you

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