

PRESS RELEASE

CAEN, 16 April 2021

All activities at the Cancérologie Nord-Ouest (CNO) Data Management Centre (CTD - Centre de Traitement de Données) are now certified ISO 9001

The CTD-CNO, located within the François Baclesse Comprehensive Cancer Centre in Caen, already certified with the 2015 version of the ISO 9001 standard for its software administration and research project data management, has just extended its certification perimeter to include biostatistics.

This international recognition attests the quality know-how and skills boasted by the CTD-CNO. This certification offers proof that the CTD-CNO has an integrated customer culture and facilitates innovation. It is a source of great pride for the teams that have worked hard for over 15 years to process data on clinical research in the fight against cancer.



From left to right:
R. Travers – Data Manager
L. Laroche – Quality Manager - Data Manager
L. Picard - Director of Quality and Risk Management
Prof. M-A. Mahe - CEO CFB
Y. Azzouzi - Trainee
A. Lelaidier – In charge of Data Management
B. Dubois - Director CTD
V. Harter - Biostatistician
C. Leroux – Biostatistics trainee
V. Delalande – Medical Assistant

What is the CTD-CNO?

Created in 2005, the Cancéropôle Nord-Ouest Data Management Centre (CTD-CNO) is a department at the François Baclesse Comprehensive Cancer Centre. As a support platform, certified by the Cancéropôle Nord-Ouest, supported by the Ligue contre le Cancer as a Clinical Research Platform and certified in 2007 by the French National Cancer Institute (INCa), the CDT-CNO contributes towards the research projects it is entrusted with, by offering its specific experience.

Since its creation, the CTD-CNO has taken on the data management of all or part of over 300 projects. Its expertise in database administration and data management is complemented by methodology and biostatistics activities. The clinical trials entrusted by partner establishments cover all fields of cancer research (radiotherapy, surgery, radiology, drugs, support care, etc.).

An entire team, convinced of the relevance and benefits of certification

In 2018, the CTD-CNO was certified ISO 9001: 2015 by Bureau Veritas Certification for its software administration and research project data management activities.

'Two of our processes were already ISO 9001-certified since nearly 3 years. We successfully drew benefit from this certification by continuously improving practice and by taking our customers' satisfaction into account. It seemed clear to us that this certification should be extended to cover our biostatistics activities,' Lucie Laroche, Quality Manager at the CTD-CNO, explains.

It is evident that this quality approach has a highly positive impact on activities, hence the CTD-CNO's wish to integrate biostatistics within the scope of its certification. The certification audit was conducted on 13 November 2020 and the new certificate entered into force on 31 March 2021.

'This certification approach, via an internationally renowned standard such as ISO 9001, not only enables us to guarantee that all our processes abide by currently applicable rules, but also offers us increased national exposure. It is also the acknowledgment of the team's hard work, the great commitment of our staff having been highlighted by the auditor,' Brice Dubois, Director of the CTD-CNO proudly adds.

'The Data Management Centre (CDT) is a leading platform for the pooling of resources to serve Research in our region (Hauts-de-France / Normandy). I am delighted that action undertaken over recent years is continuing to evolve and that the CTD is constantly improving to serve the scientific community in the Cancéropôle Nord-Ouest area and beyond,' indicates Prof. Guy Launoy, President of the Cancéropôle Nord-Ouest.

'The extension of the CTD-CNO's ISO 9001 certification perimeter reinforces a number of existing approaches towards increased quality at the François Baclesse Comprehensive Cancer Centre, and contributes towards developing the establishment's quality culture, endorsed in particular by its European certification as a Compréhensive Cancer Centre. Since 2018. The team has successfully integrated ISO certification tools and methods to invest

them in the coordination and the improvement of the department's activities. Certifying our biostatistics activity was a new challenge; it relied on a solid quality system and a dynamic and committed team,' Dr Laurence Picard, Director of Quality and Risk Management at the François Baclesse Comprehensive Cancer Centre affirms.

'Excellence in research cannot dispense with skills in data processing and analysis. With its ISO 9001 certification extended, the CDT - a platform at inter-regional level - has reinforced acknowledgment of its expertise and its attractiveness among research teams. It contributes towards our establishment's influence, with a permanent priority on quality to benefit patients,' Professor Marc-André Mahé, CEO of the François Baclesse Comprehensive Cancer Centre highlights.

For further information:

About the Cancéropôle Nord-Ouest Data Management Centre



The CTD-CNO is a platform, the activity of which is entirely devoted to clinical research (clinical trials, diagnostic or prognostic studies), in biology and epidemiology (surveys and cohort studies). At inter-regional level, it provides healthcare establishments with a secure, networked and computerised data management tool, together with all the necessary skills for its successful exploitation.

The centre's staff can accompany investigators throughout each and every phase of a study, from project design to valorisation of results. The CTD-CNO was granted ISO 9001 :2015 certification on 29 March 2018.

- www.ctd-cno.org

About the Cancéropôle Nord-Ouest



The Cancéropôle Nord-Ouest's mission, renewed within the framework of the 2018-2022 targets and performance contract concluded with the INCa, is to accelerate the research / innovation / treatment cycle for the benefit of patients, through a concerted continuum of care-research, knowledge transfer and therapeutic application:

- By improving the structuring of skills and infrastructures at inter-regional level, with an objective of multidisciplinary, critical mass and scientific excellence.
- By implementing original, ambitious and innovative research programmes, relying on articulation and complementarity between the various research disciplines.
- By coordinating the implementation of integrated research, in a logic towards transfer of and towards patients, and of patient access to clinical innovations.

- www.canceropole-nordouest.org

About the François Baclesse Cancer Centre



Located in Caen, the François Baclesse Comprehensive Cancer Centre is Western Normandy's (Calvados, Orne, Manche) specialised cancer hospital (CLCC). It is a private health institute of public interest (ESPIC), caring for any patient presenting with suspected or confirmed cancer.

A member of UNICANCER, the François Baclesse Comprehensive Cancer Centre's activity focuses entirely on cancer diagnosis and treatment. The centre also assures a mission of cancer research and education.

As a stakeholder in public hospital services, the centre applies neither private sector fees nor fee enhancement, but exclusively standard social security fees.

A public interest establishment, it may receive donations and legacies, totally exempt from taxation.

Key figures -2019: 1,042 salaried employees, including 137 doctors and scientific staff members; 231 beds; 27,563 patients treated, including 7,657 new patients; 70,500 consultations; 39,754 full days of medical hospitalisation; 2,395 outpatient surgery days; 20,925 medical day hospital days; 55,678 radiotherapy sessions; 2,373 protontherapy sessions; 166 clinical trials open to inclusions and 534 patients included in clinical trials.

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