

A close-up photograph of a white medical device, likely a patient warming unit. The central feature is a large circular opening with a dark inner ring. To the right, there is a control panel with several small, round buttons. The device has a clean, clinical appearance with some warning labels and a small indicator light.

BIONT

# COMPANY PROFILE

**BIONT is a state-of the-art facility for production of radiopharmaceuticals and provision of healthcare in the field of nuclear medicine.**

**The company also operates one of the largest PET/CT centres in Slovakia.**

**The production of radiopharmaceuticals by BIONT exceeds three-quarters of the whole Slovak PET market.**

# BIONT

BIONT, a.s. is a state-owned joint stock company acting in the field of nuclear medicine with an emphasis on Positron Emission Tomography (PET). The company's key objective is to manufacture and distribute radiopharmaceuticals for logistically accessible PET centres and provide PET/CT and SPECT/CT examinations for patients from the Slovak Republic and abroad. Its main activities are also closely related to research and development of the preparation of radionuclides, radiopharmaceuticals, and production equipment, as well as education, training and dissemination of the company's proprietary know-how.



PET/CT and SPECT/CT  
examinations



Production and distribution  
of radiopharmaceuticals



Research and development  
of radionuclides



Education, training, and  
dissemination of know-how



# PET CENTRE

**P**ET centrum BIONT, a.s. (PET Centre) has been a **leading provider of PET/CT diagnostics in the Slovak Republic right from the beginning of its operation.** Currently, it performs more **than 3,000 PET/CT examinations per year using two PET/CT tomographs.** The most common examinations involve oncology patients with lymphoproliferative diseases, brain tumours, tumours of the gastrointestinal tract, and malignant melanoma.



A hand is pointing at a grid of SPECT/CT tomographs. The tomographs are arranged in a 3x3 grid. Each tomograph shows a cross-section of the body, likely the abdomen, with various organs visible. The text is overlaid on a teal background in the center of the grid.

One SPECT/CT  
tomograph provides  
around 1000  
scintigraphic  
examinations annually.

Besides the most widespread **radiopharmaceutical 18F-FDG**, there are **nine more positron radiopharmaceuticals** used for diagnostics today. In 2013, the routine examinations of patients with brain tumours began with radiopharmaceutical **11C-Methionine**, and later with **18F-Fluoroethylytyrosine**.

Since November 2014, the centre uses **18F-Choline** and **11C-Choline** for diagnostics of recurrent prostate cancer, hepatocellular carcinoma, and parathyroid adenoma.

In 2017 came next the examinations of neuroendocrine tumours with **68Ga-DOTATOC** and **18F-DOPA**, and in 2018 examinations of cancer prostate with **68Ga-PSMA**.

However, the centre's **considerable experience with non-oncology PET diagnostics** deserves a mention as well. It is mainly used in patients with fever of unknown origin, vasculitis, sarcoidosis, and in the localisation of the epileptogenic zone in patients with refractory epilepsy. In differential diagnostics of dementia, BIONT has been using radiopharmaceuticals **18F-Flutemetamol** and **18F-Florbetaben** since 2015.



In the field of conventional nuclear medicine, medical department focuses mainly on the diagnostics of infection using labelled autologous leukocytes, **diagnostics of Parkinson's disease, parathyroid scintigraphy**, but it also provides common examinations such as **skeletal scintigraphy or lymphoscintigraphy (sentinel lymph node mapping)** in patients with malignant melanoma and breast cancer.



# NUCLEAR MEDICINE, PRODUCTION AND QUALITY CONTROL OF RADIOPHARMACEUTICALS





In the short time since its foundation on 21 January 2005, the company ranked itself among prominent producers of PET radiopharmaceuticals, as well as outpatient healthcare providers in nuclear medicine.

The examinations of patients using the PET/CT and SPECT/CT tomographs started already in the first year of the company's operation. At the time, **the pilot production of 18F-Fludeoxyglucose (18F-FDG)** started and **already in 2006 BIONT was supplying 18F-FDG to all PET centres in Slovakia.**

In 2009, BIONT started its **regular supplies of radiopharmaceuticals** also **abroad**. Naturally, the company complies with the principles of the **Good Manufacturing Practices, Good Distribution Practice**, and uses a certified **Quality Management System** according to ISO 9001:2015.

Development of revenues from the sale of radiopharmaceuticals and licenses in the years 2018-2020 (in M€)




The company product – radiopharmaceutical **biontFDG** is currently **registered not only in Slovakia, but also in two other EU member states** – in the Czech Republic and Austria. **Another product (18F) Fluorocholeline BIONT has been registered in Slovakia since 2020.**

The product range is gradually expanding due to the increased interest in new radiopharmaceuticals, which requires continual improvement and innovation of manufacturing processes and equipment, as well as development of the quality control methods of the produced radiopharmaceuticals.

Besides the daily **production of 18F-FDG, the company supplies its customers** on a weekly basis with radiopharmaceuticals **18F-FET, 18F-PSMA-1007, 18F-Choline**, and radiopharmaceutical **precursor 64CuCl<sub>2</sub>** used for the preparation of **64Cu-DOTA-PSMA** or **64Cu-DOTA-TOC**. In addition, there are other radiopharmaceuticals being produced, such as **11C-Methionine, 11C-Choline, 18F-DOPA, 68Ga-DOTA-NOC, 68Ga-PSMA-11, and 64Cu-Acetate.**





**All radiopharmaceuticals are produced in accordance with cGMP and radioisotopes  $^{18}\text{F}$ ,  $^{11}\text{C}$ ,  $^{64}\text{Cu}$ , and  $^{68}\text{Ga}$  are produced using cyclotron.**

All radiopharmaceuticals are subject to a strict quality control guaranteed by a separate department which ensures control of input material for production, as well as quality control of the final products. The produced medicines are released for clinical use only after all necessary parameters have been checked according to the European Pharmacopoeia.

**For the patients of our own PET Centre, we offer also  $^{68}\text{Ga}$ -DOTA-TOC and  $^{68}\text{Ga}$ -PSMA-11 prepared from  $^{68}\text{Ga}$  eluted from generator and made ready by using kits.**

**The company product – radiopharmaceutical biontFDG is currently registered not only in Slovakia, but in two other EU member states.**



# RESEARCH & DEVELOPMENT

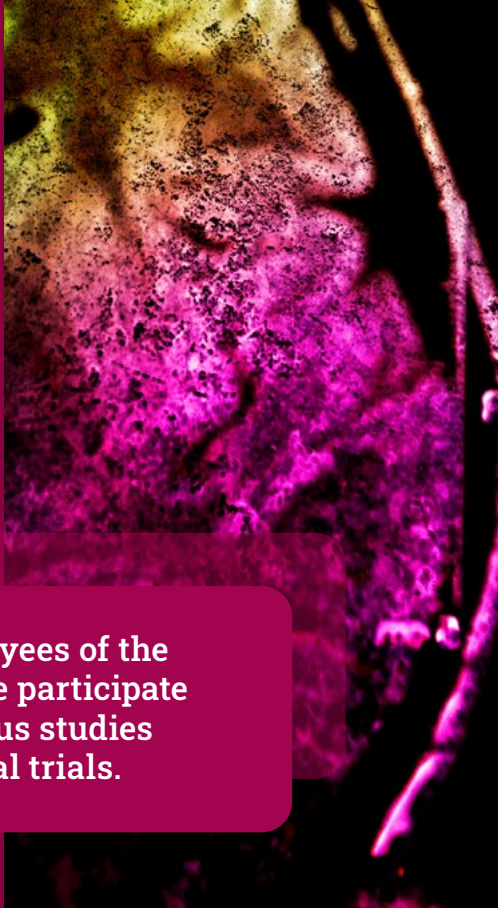
**R**esearch and development focus on the production of positron radiopharmaceuticals and their further use in nuclear medicine, especially for PET diagnostics.

The research is also aimed at the preparation of positron radionuclides, the radiochemical purification of radionuclides for labelling, and the preparation of precursors. An integral part of the research is the development and construction of technological equipment and process automation, that enables the manipulation with highly radioactive materials. The **outcome** of the research activities is the **preparation of production technology for radionuclides  $^{44}\text{Sc}$ ,  $^{64}\text{Cu}$ ,  $^{68}\text{Ga}$ , and  $^{89}\text{Zr}$** . These radionuclides together with the standard PET radionuclides ( $^{11}\text{C}$ ,  $^{18}\text{F}$ ) are used for labelling new prospective radiopharmaceuticals, which expand the possibilities of PET diagnostics.



In the early stages of research, preclinical tests of selected radiopharmaceuticals were carried out using a microPET laboratory tomograph. Its use was later transformed into the research area of physiological processes in plants. This research then continued at the joint facility with the University of St. Cyril and Methodius in Trnava.

**The employees of the PET Centre participate at numerous studies and clinical trials.**

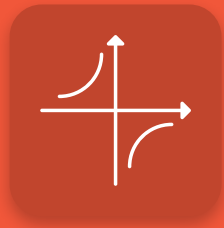




The development and validation of the quality control methods form an integral part of the development of new radiopharmaceuticals. The research activities are implemented in collaboration with prominent world-class facilities as well as with the International Atomic Energy Agency.

The employees of the PET Centre participate at numerous studies and clinical trials. In cooperation with the National Cancer Institute in Bratislava we perform PET/CT and gammagraphic examinations initial staging of the oncological diseases and in the evaluation of the effects of the treatment for the new types of chemotherapy. We also perform diagnostic examinations of prostate cancer for various urological facilities.

The PET Centre provides brain scans for clinical trials of the new types of treatment of neurodegenerative diseases for the neurological and psychiatric clinics of the University hospital in Bratislava.



# EDUCATIONAL ACTIVITIES





**T**he company shares its expertise acquired in years of its existence via **short-term trainings and long-term internships** organized by IAEA or based on direct agreements with interested institutions.

**Another form of the dissemination of our know-how is the cooperation with Slovak universities in research and pedagogy.** Since 2013, we have been collaborating with the Faculty of Natural Sciences of the **University of St. Cyril and Methodius in Trnava** in the research of physiological processes in plants, that included the defence of one habilitation thesis, two dissertations and several diploma and bachelor's theses.

Currently, the **Faculty of Materials Science and Technology of the Slovak University of Technology located in Trnava** is also participating in the collaboration. There have been **bachelor's, master's, and doctoral theses** accomplished at BIONT for students of the following faculties:



Faculty of Pharmacy, Faculty of Natural Sciences, and Faculty of Mathematics, Physics and Informatics of the Comenius University, and the Faculty of Electrical Engineering and Information Technology of the Slovak University of Technology in Bratislava. The BIONT employees provide **lab training** on quality control of radiopharmaceuticals for students of the Faculty of Pharmacy of the Comenius University.

Some of numerous educational activities are the **annual participation of the BIONT employees at the Science Fair** for adolescents, and last but not least, the **expert input and consultancy at the construction of new centres** focused on the production of positron radionuclides and radiopharmaceuticals.

The BIONT PET Centre currently offers an **undergraduate practical training for students of the Department for radiological assistants of the Slovak Medical University.**

At the facility, we also organise **postgraduate training stays for doctors enrolled in specialized training in the field of nuclear medicine.**



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solventných  
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## CERTIFICATES & AWARDS

## PARTNERS



MINISTERSTVO  
ŠKOLSTVA, VEDY,  
VÝSKUMU A ŠPÓRTU  
SLOVENSKEJ REPUBLIKY



MINISTERSTVO  
ZDRAVOTNÍCTVA  
SLOVENSKEJ REPUBLIKY



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## BIONT, a.s.

Karloveská 63  
842 29 Bratislava  
Slovak Republic

Company ID: 35 917 571  
VAT ID No.: 2021932748

[biont@biont.sk](mailto:biont@biont.sk)  
[www.biont.sk](http://www.biont.sk)

Sale and distribution of radiopharmaceuticals: [order@biont.sk](mailto:order@biont.sk)  
PET Centrum: [pet@biont.sk](mailto:pet@biont.sk)