# Description of the specialization

## SECTION I – NEW PRODUCTS AND TECHNOLOGIES

### Research and development of medicinal products

1. Methods, tools and processes leading to medicinal products: chemical medicines (innovative and generic), biologicals and biosimilars.
2. New active substances, new applications of known active substances and combination thereof.
3. New forms of medicines, both single and multicomponent.
4. Development of innovative formulations, nanostructures, carriers for medicines.
5. Technologies aimed at achieving controlled result, extended administration, release or delivery of drug substances.
6. Bio-catalysis in processes of manufacturing of medicinal products (new cell models, expressive systems, methods for clone selection, culture media and processes).
7. Methods aimed at improvement of drug pharmacodynamics (dose reduction with reaching analogical therapeutic effect) and pharmacokinetics.
8. Technologies aimed at reducing costs or enhancing efficiency, safety and effectiveness of the therapy, new technologies increasing the likelihood of patients compliance with physician instructions.
9. Application of new cell models with better properties, in vitro and in vivo models, purification methods and assessment of the effectiveness and safety of biological and biosimilar medicines - compared to the ones used in reference products.
10. Synthetic biology in medicine - use of the biological synthetic systems (including e.g. modified microorganisms, cell lines) to produce new drugs, vaccines and therapeutic solutions (e.g. cell and gene therapies).

The area includes development of medicinal products from the discovery stage, through the pre-clinical to the clinical stage and registration.

### Advanced therapies medicinal products (ATMP) and biologicals

Work on novel use of stem and/or progenitor cells and/or other cells/tissues transplanted both as autologous and allogeneic transplants. Research and development projects can be fundamental, pre-clinical as well as clinical in nature.

1. ATMP medicinal products based on the use of stem, progenitor and other cells (e.g. mature cell from specific organs, immune system cells, etc.) delivered

directly to the organism or with the use of carriers [e.g. encapsulation, biodegradable membranes, scaffold with active substance or human or animal material, or covered with cells from tissue establishment – stem cells and others; other scaffolds, patches, stents and implants, etc.
2. Biological products including innovative use of protein products (e.g. cytokines, chemokines, hormones, antibodies, genetic vector, viruses; products with xenogeneic cells).
3. Isolated human cells for the purposes of alternative therapies.
4. Tissue establishments of medicinal products necessary for the manufacturing and/or storage process which meet the requirements needed for pre-clinical and clinical researches: GMP/GLP/GCP.

**Research and development of INNOVATIVE food supplements and foods for particular nutritional uses**

1. Methods, tools and processes leading to innovative food supplements and foods for particular nutritional uses.
2. New bioactive substances of better bioavailability and tolerance used for prevention, including diseases of affluence, and for the purpose of enhancing efficiency of the proper therapy.
3. New technological solutions allowing improvement of assimilability of substances contained in food supplements and foods for particular nutritional uses.
4. Technologies aimed at achieving controlled result, administration, release or delivery of substances contained in food supplements and foods for particular nutritional uses.

**Bioinformatics**

Models, algorithms and software to search for molecular targets of therapy, molecular modelling of structures, drug design and disease diagnostics.

**Medical appliances and devices**

1. Development, design, implementation and production of innovative medical, including dental, appliances, instruments and devices, used for conducting or assisting therapy or medical diagnostics, aimed at: realisation of new forms of therapy or diagnostics, improvement of therapy or diagnostics effectiveness, mitigation of therapy side effects, reduction of therapy or diagnostics costs, decrease of functional limitations.
2. Development and implementation of technological solutions allowing realisation of new methods: of treatment, compensation of functionality limitations, including mobility and perception disability, rehabilitation, prevention or

improvement of efficiency of methods existing in these disciplines.

The area includes diagnostic, therapeutic, rehabilitation and compensation apparatus.

**Health technologies**

1. Technologies of regenerative medicine.

1. Developing and implementing of new techniques of tissue engineering and regenerative medicine.
2. Development of technologies and tools aimed at the process of organs, tissues and cells regeneration.
3. Creation of new biomaterials for the repair of damaged cells and tissues.

2. Artificial organs.
   Innovative appliances, instruments, medical devices, including implants intended for the replacement or support of impaired organ functions for therapeutic purposes covering the use of technical device (prosthesis) as temporary support of failing organ for the time of treatment for regeneration and return of efficient function and/or as long term or permanent support/replacement of the function of failing organ.

   The area includes, apart from medical devices and instruments which are direct elements of artificial organs, technical support devices, including monitoring the work of artificial organs, necessary for improving safety, effectiveness, efficiency and comfort of the life of patient being treated with the use of artificial organs, in particular implantable sensor monitoring the work of supported organs and other biological functions of the patient and the work of artificial organs; systems allowing remote monitoring of artificial and supported organ work and patient monitoring, leading to increasing safety and effectiveness of patient with artificial organ at home and in work environment.

3. Material technologies in medicine

   Development of new materials which will be used for production of implants, artificial organs or for other medical uses, or new technologies for material production. This area includes also tissue and genetic engineering allowing to produce hybrid implants.

IT medical tools

1. Design and development of IT solutions used for collecting and analysing medical data for the diagnostic and therapeutic purposes, in particular IT systems

for collecting, processing and analysing medical data and information by text, sound, picture analysis or other forms necessary for diagnosing, treating and monitoring of patients.
2. Design and development of IT solutions allowing integration of different IT systems used in the healthcare system, facilitating safe collection and storage of medical data, including sensitive personal data, development of algorithms supporting medical decisions, assisting personalisation, coordination and optimisation of healthcare.
3. Design and development of IT solutions assisting disease diagnosing, in particular systems based on artificial intelligence, complex inference systems or systems based on computer simulations at different levels of complexity (from simulations at molecular or cellar level, through organ level simulations to simulation of the organism as a whole).
4. Design and development of IT solutions allowing treatment assistance based on computer simulations at the planning stage and stage of conducting therapy.

Proposed activities in this discipline should use and create innovative IT solutions, software advanced methods of calculation and simulation, including machine learning algorithms and algorithms of Big Data analysis, developed jointly with healthcare professionals and payers.

The area DOES NOT INCLUDE IT systems for the needs of accounting medical services or collecting data under the law and not connected directly with diagnostics and treatments**.**

## SECTION II – DISEASE DIAGNOSTICS AND THERAPY

### I. Diagnostic imaging and diagnostics based on other detection techniques

Modern and efficient disease diagnostics based on imaging techniques and novel detection techniques is:

1. Identification, validation, development and implementation of new biomarkers of diseases of affluence on the basis of diagnostic imaging methods in groups of well characterised people (e.g. with disease predisposition, at an early stage of disease).
2. Development and use of modern methods of diagnostic imaging and diagnostics based on other techniques, allowing early identification of structural lesions within systems and organs during the course of diseases of affluence and dynamic functional

assessment connected to it.
3. Validation of already identified diagnostic markers/tests based on diagnostic imaging methods of diseases of affluence in big populations of risk groups and/or general population.

The results of designing and implementing activities in place should be introduction to the market
(or preparation for such introduction) of new clinical diagnostics methods and markers/tests (or validation of already existing) based on diagnostic imaging or based on other techniques, or more efficient diagnostic algorithms.

**II. Markers/tests**

Design of innovative and efficient methods for diagnostics of diseases of affluence:

1. Markers/tests of early detections of predispositions to diseases of affluence allowing prevention of disease development or delaying its occurrence or slowing/mitigating its progress.
2. Markers/tests of early detections of diseases of affluence allowing to start treatment sufficiently in advance.
3. Markers/tests allowing conducting personalised therapies of diseases of affluence.

A pre-condition for the design of new diagnostic tests is identification of novel markers of diseases of affluence on the basis of tests conducted in groups of well characterised people (e.g. with disease predisposition, at an early stage of disease). Research and development projects aimed at design for the needs of implementation in the area of ‘Diagnostics’ include new sensitive and specific markers, validation of already identified markers related to diseases of affluence in big populations of risk groups and/or general population. Progress in development of new methods for diagnosing diseases of affluence is based on new research models of diseases of affluence and on innovative technologies, especially of multi-scale nature, based on genomics, transcriptomics, epigenomics, protoemics, metabolomics. The results of activities in place should be introduction to the market or preparation for such introduction of new diagnostic markers/tests, medical devices, more efficient diagnostic algorithms or validation of already existing methods and tests.

**III. Telemedicine**

1. Creating solutions, technologies, products, tools, applications, algorithms which by using modern information and communication technologies will improve already existing ones but above all will create new methods of acquisition, analysis, archiving and safe exchange of information about patient’s health condition both between the patient and medical professional and groups of

medical professionals which are in a geographically distant places. The direct goal of solutions being created in this model should be support connected to transmission of safe data and medical information for diagnostic and therapeutic processes for collecting, processing and analysing medical data and information by text, sound, picture analysis or other forms necessary for diagnosing, treating, monitoring patients and information exchange between medical professionals and groups of medical professionals.

2. Design of innovative solutions based on information and communication technologies (ICT) used as methods for remote, non-inasive and safe collection and exchange of information about health condition between healthcare system and ill or healthy person. Proposed solutions should be applicable to: diagnostics; therapy, including invasive treatments performed at a distance; prevention; medical rehabilitation; coordinated care; health condition monitoring with the use of devices, detectors and accessories; registration and analysis of biological signals of significant importance for health; improvement of following instructions, including keeping up to the therapeutic plan; postoperative and posttraumatic rehabilitation; recreational physical activity; education of ill and healthy people with promoting healthy behaviours; improvement of the quality of life of ill people and people being diagnosed; professional education of healthcare staff; creation of large medical data databases; integration and unification of dispersed medical data systems with systems of Electronic Medical Records. An important goal of innovative activities in the field of telemedicine should be design and use of ICT solutions and medical devices which help to lower the costs of healthcare and/or improve the quality of provided services and/or facilitate and shorten the time of access to healthcare system and/or ensure health safety for elderly people with chronic diseases and disabilities, and its comfort and simple use for end users.

**IV. Coordinated health care**

Coordinated health care includes activities covering such stages of healthcare as: health promotion and prevention, risk and disease progression assessment, therapies and rehabilitation which may be integrating, comprehensive and continuous in nature, as well as coordinated education in relation to coordinated healthcare on different levels of education and addressed to different groups of recipients.

The area includes:

1. Early detection of somatic genome changes (e.g. in the DNA) and biochemical (e.g. concentration of microelements) useful in identification of high risk groups of falling ill of genetic disorders (including in particular tumors) as well as in detection of genetic disorders at early stages.

2. Development and implementation of population-based screening programmes and prevention programmes allowing diagnosis and start of treatment at the earliest stage possible.
3. Identifying risk factors of distress related to disadvantages of civilisation which directly or indirectly increase the number of mental disorders.
4. Healthy diet in health and illness, and shaping of healthy behaviours in different aspects of life with the use of universal design concept.
5. Development and implementation of technological solutions allowing realisation of new methods: of compensation of functionality limitations, including the ones resulting from mobility and perception disability, prevention or improvement of efficiency of methods existing in these disciplines.
6. Assessment of risk and/or disease progression covering aspects of clinical, social, psychological evaluation, genetic history, way of life, including dietary and lifestyle patterns.
7. Activities ensuring preservation and promotion of work-life balance, especially by dissemination of mental hygiene and activities lowering stress, allowing to stay mentally and physically healthy and reducing or slowing progression of diseases which have already occurred.
8. Methodology for risk assessment in terms of: activity decreasing or increasing risk of diseases; individualised cognitive and mental training allowing early detection of risk of mental disease or disorder occurrence; socio-economic determinants directly affecting disease risk and integration of these factors with medical and clinical factors of disease process.
9. Assessment of risk and/or rare, chronic, civilisation diseases progression in which the possibilities of improving effectiveness and/or safety of pharmacovigilance are limited, including multi-specialistic and innovative care, allowing extension and improvement of the quality of life taking into account economic results.
10. Coordinated programmes and therapies taking into account all significant elements of treatment process with the aim of its optimization, integration and adaptation with personalised needs of patients by connecting to interventional and conservative treatment in the form of, among other things, and pharmacovigilance, psychotherapy, physical activation methods, supporting mental condition and hygiene, as well as change or modification of dietary pattern taking into account the personalised enteral and parenteral nutrition and correct diet.
11. Joint activities and programmes of partners such as medical and psychological centres; physiotherapy, psychology and/or psychotherapy, dietetics specialists; social workers; employers; leading to education for changes of lifestyle, speed of life, life hygiene (including psychological), covering also the generation of services and/or products of healthy qualities and psychologically healthy

behaviours needed in this area.

12. Research on new civilisation disease therapies based on innovative technologies of personalised medicine (from the discipline of genomics, transcriptomics, epigenomics, protoemics, metabolomics) and personalised therapy based on biopsychosocial model (consisting of methods for work with patient taking into account psychological-psychotherapeutic profile, life conditions, available material and intangible support, and other).
13. Treatment of chronic, rare diseases and people with disabilities and physical and intellectual indispositions covers multi-specialistic, coordinated care for patient together with their family.
14. Development of ICT tools which aim at information exchange of patient's health condition, coordination of activities between medical specialists at different treatment centres and education of specific professional groups of medical staff and patient's social environment. It also covers telecommunications engineering solutions causing increase of patient's involvement in treatment process by self-evaluation of health condition, evaluation of treatment process and cooperation with medical team taking coordinated care of the patient.
15. Implementation of integrated rehabilitation activities and programmes ensuring recovery
and return to social and professional activity within the framework of cooperation of specialists from different disciplines, including
medicine, telemedicine, medical engineering and compensation technologies, physiotherapy, psychology, dietetics, occupational counseling, law (constituting interdisciplinary teams).

**V. New preventive and/or therapeutic objectives**

Therapy of civilisation diseases should be based on design and implementation of:

1. New therapies for civilisation diseases based on medicinal products (chemical, biological, biosimilar, innovative and generic medicines).
2. Algorithms for dealing with patients on the basis of personalised diagnostics results.
3. Mechanisms of conducting selection and validation of effectiveness of therapeutic chemical units.
4. Protocols of monitoring and assessment of therapeutic activity effectiveness, e.g. on models of patient's cell lines.

The condition for proposing and preparing for implementation of targeted (personalised) therapy is conceivably complete identification of disease origin, e.g. genetic, metabolic origin, etc. as well as possibilities of prediction and assessment of the effectiveness of proposed therapy on cell line, bacteria or in silico models

with simultaneous possibility to assess the effectiveness and stability of the proposed therapy. Development and implementation of new targeted therapies of unique importance, as well as combined therapies giving the possibility to improve the quality of patient’s life in comorbidities with simultaneous assessment of its effectiveness, monitoring
and change during conducting the therapy.

Progress and development is closely related to the development of DIAGNOSTICS and uses its results, introducing new, unique models for therapy effectiveness assessment which eliminate negative effects for the patient.

**VI. Clinical research**

Clinical research includes:

1. Prospective clinical research including randomised research involving patients and/or healthy people, being conducted for the assessment of effectiveness and/or safety of new, innovative therapeutic methods with the use of medicines and/or medical devices. Projects in the field of clinical research may take into account biopsychosocial models, also without the use of pharmacovigilance, being therapeutic, diagnostic, screening, preventive, prognostic or epidemiological in nature.
    1. Clinical research of early stages, aimed at the safety assessment of pharmacokinetics and pharmacodynamics, determining optimal dosage, etc. new medicines and treatment methods, and assessment of new diagnostic methods. This concerns especially innovative, personalised, targeted therapies and identification and verification of the proper prognostic biomarkers.
    2. Clinical research of later stages, aimed at the effectiveness assessment of medical intervention and/or other therapeutic, or diagnostic method and observational and epidemiological studies.
    3. Studies related to biopsychosocial factors; rehabilitation and/or physiotherapy; psychotherapy (including especially cognitive and behavioral methods); quality of life determined by health condition, social support, motor activation, healthy diet, cost efficiency of non-pharmacological therapy and studies on models of coordinated care of ill people.
    4. Studies on technology of clinical research. Design of innovative technological solutions (models, processes and devices) used to increase safety of patients, lower costs, optimize number of participants, increase assessment precision and reduce time of clinical research realisation.

The solutions should concern:

- models and software used to analyse massive datasets (Big Data) with the purpose of profiling prediction studies (e.g. identification of units – candidates for medicines),
  in bioinformatics, studies related to identification of innovative medical procedures and standards (secondary data analysis) and in screening within clinical research;
- designing new devices for use in clinical research (e.g. lab-on-the-chip, in silico) and devices allowing to collect, transmit and process biosignals;
- information and communication technologies (ICT) for collecting data and monitoring participants of clinical research;
- legal and administrative solutions aimed at efficient and fast obtaining of authorisations and concluding contracts allowing effective and safe conduct of clinical research;
- facilitations in designing, documentation assessing and financing clinical research of early stages related to new therapies developed in Polish laboratories or by Polish institutions.

## SECTION III – MANUFACTURE OF PRODUCTS

### I. Biological, biosimilar, INNOVATIVE, generic MEDICINAL products and medical devices, food supplements and foods for particular nutritional uses

1. Methods for conducting production process, designing new methods for production of biotechnological medicines including biosimilar and biobetter medicines, i.e. products manufactured with the use of living organisms.
2. Development of manufacturing technologies of generic, biosimilar medicines and active substances not used in development and production of reference medicines.
3. New, innovative, improved technologies of: storing (biobanks) master clones and working clones, biocatalysis, fermentation, purification, filtration, packaging, storing and qualitative study of biological medicines.
4. Design of new technologies for manufacturing innovative and generic medicinal products, biological and biosimilar medicines, medical devices, food supplements and foods for particular nutritional uses.
5. Methods for implementation of modern production technologies and formulation improvement resulting in the change of pharmacodynamic and pharmacokinetic properties.
6. Preparations manufacturing based on pharmaceutical technologies.

7. New technologies of delivering active substances to patient’s organism including use of modern carriers in pharmaceutical technology.
8. Technologies of modified release of active substances.
9. Manufacturing of nanostructured materials for medical purposes.
10. Technologies for manufacturing single-component and complex products with the use of modern formulation.
11. Manufacturing of products used for new indication or dosage with the use of known active substance.
12. Manufacturing of new medicine forms based on known substances or using modified or improved technologies of their administration.
13. Searching for and manufacturing of innovative and more efficient expressive systems, cell lines, culture media and methods for biocatalysis, fermentation, purification, filtration, packaging, storing and qualitative study of biological medicines.
14. Development of innovative analytical techniques, methods of synthesis and isolation of impurities of medicinal products.
15. Design and validation of new analytical methods for active substances of medicines and proprietary medicines.

**II. ACTIVE substances of medicinal products (API)**

Definition: substances of indicated biological activity and declared pharmaceutical usefulness, of natural or synthetic origin, in particular: secondary metabolites or their compositions, materials of biopolimeric nature manufactured with biotechnology methods and biosimilar substances, natural substances manufactured with methods of chemical synthesis, chemical conjugates and bioconjugates, synthetic substances, molecular and supramolecular complexes, nanomaterials, radiopharmaceuticals, molecular
and diagnostic probes. In particular, innovative forms of active substances of generic medicines –
including nanoparticles, nanoformulations and nanopreparations, new pharmaceutically acceptable salts and complexes of different degrees of dispersion or immobilisation on target surfaces or particles.

1. New technologies for manufacturing active substances, innovative, generic and biological medicines with the use of materials, solvents, catalysts and new processes.
2. New technologies for manufacturing of active substances of medicines reducing negative effect
on the environment (e.g. taking into account the principles of green chemistry).

New technologies for manufacturing of active substances of medicines improving their

quality (content and impurity profile in the context of substances and preparations stability) and/or reducing time

**III. Medicinal products for external application, dermatological and cosmetic**

Process and product innovation in relation to manufacturing new active substances and novel formulations used in the cosmetic industry. In particular, technologies for manufacturing active substances which are sustainable and do not exploit the environment e.g. cell, tissue and complex cultures (including stem cell cultures, microorganisms cultures, including microalgae). Searching for new active substances of various origin, chemically or biotechnologically modified and searching for new application areas of already known active substances. Searching for new active substances used in cosmetics of high therapeutic activity and design of technologies for their manufacturing. Developing novel methods for production of active substances used in cosmetics under laboratory conditions.

1. Innovative protective cosmetics.
2. New, innovative active substances used in cosmetics of various origin, chemically and biotechnologically modified, of high biological activity in prevention and health protection.
3. New, innovative basic substances of cosmetic compositions.
4. New test methods for the assessment of safety, effectiveness and mode of action of active substance used in cosmetics and finished cosmetic product which contains the substance.

Innovative forms of delivering cosmetic active substance.

**IV. Natural medicinal products**

Research on innovative preparations of natural origin which have therapeutic effect in the following conditions:

1. Prediabetes and prehypertension state.
2. States endangering to destabilise the plague (heart attack and stroke prevention).
3. States related to chemotherapy and radiotherapy, and immunosuppressive therapy.
4. Chronic inflammations.
5. States related to chronic hepatitis, pancreatitis and gastrointestinal diseases – of small and large intestine.
6. Research on the creation of new forms of natural medicinal products – micro- and nano-technologies.