



REGULATIONS OF THE PRIX GALIEN POLAND 2026 CONTEST

PREAMBLE

The Prix Galien Contest, inaugurated in 1970, pays tribute to the legacy of Claudius Galen — an outstanding anatomist, philosopher, researcher and writer who left a lasting mark on the history of medicine. His spirit of pioneering knowledge and dedication to patient welfare remains present in every edition of the Contest.

Prix Galien, as a prestigious distinction, celebrates innovative products and scientific discoveries that not only save lives but also significantly improve patients' quality of life. The award represents a global symbol of excellence in medicine and health sciences, comparable to the Nobel Prize.

The Prix Galien Poland Contest is the Polish edition of this international initiative, focusing on recognizing scientific innovations available on the Polish market. Its objective is to promote the very best achievements in accordance with the highest standards established by the Prix Galien Founding Committee.

These Contest Regulations include all necessary guidelines regarding participation and evaluation, ensuring fairness, transparency and professionalism throughout the entire process of selecting the Laureates.



§1

GENERAL INFORMATION

- 1.1. The Prix Galien Poland 2026 Contest (hereinafter referred to as the “Contest”) is the only official Prix Galien contest organized in the territory of Poland, recognizing the most significant innovations in pharmaceuticals and medicine, in accordance with the license granted by The Galien Foundation, Inc. – 99 John Street Suite 2502, New York, NY 10038.
- 1.2. The Organizer of the Contest is the Foundation for Innovation in Medicine and Pharmacy with its registered office in Warsaw, ul. Domaniewska 44, 02-672 Warsaw, entered in the National Court Register maintained by the District Court for the Capital City of Warsaw in Warsaw, XIII Commercial Division of the National Court Register, under KRS number 0001081174, NIP 5214052907, REGON 527456628 (hereinafter referred to as the “Organizer”).
- 1.3. The Contest shall be organized and conducted in accordance with these regulations (hereinafter referred to as the “Contest Regulations”).
- 1.4. The Contest Regulations are available on the Contest website: www.prixgalienpolska.com.

§2

OBJECTIVES OF THE CONTEST

- 2.1. The objective of the Contest is to select and reward, among the Contest Participants referred to in §4 section 4.7 below, the most recognized innovations in pharmaceuticals and/or medicine in the categories described in §7 of the Contest Regulations (hereinafter referred to as the “Contest Laureates”).
- 2.2. The selection of Contest Laureates shall be carried out by a group of independent experts appointed by the Organizer (hereinafter referred to as the “Contest Committee”), operating under separate rules governing its work (hereinafter referred to as the “Committee Rules of Procedure”).



§3

CONTEST PARTICIPANTS

3.1. The Contest is open to natural persons, legal persons or organizational units without legal personality that possess legal capacity and meet the following conditions:

- (a) they have achievements in the field of medicine and/or pharmacy that may qualify within the Contest Categories specified in §7 of the Contest Regulations as breakthroughs in the diagnosis, treatment or prevention of diseases in humans;
- (b) they submit an application to participate in the Contest in accordance with the requirements specified in the Contest Regulations and Appendix No. 1 to the Contest Regulations;
- (c) they are not in any way affiliated with the Organizer.

(hereinafter referred to as the “Contest Participants”).

§4

APPLICATION AND PARTICIPATION IN THE CONTEST

4.1. Applications to the Contest may only be submitted by persons authorized to represent the Contest Participant.

4.2. In order to submit an application to the Contest, it is necessary to properly complete and submit:p

- (a) a signed Agreement between the Organizer and the Contest Participant;
- (b) confirmation of payment of the required fee or fees indicated in §11 of the Contest Regulations;
- (c) Application Documentation described in detail in Appendix No. 1 to the Contest Regulations (hereinafter referred to as the “Application Documentation”), appropriate for the Contest Category selected by the Participant as described in §7 of the Contest Regulations

(the above documents jointly constitute the Application Form).



- 4.3. After expressing interest in participating in the Prix Galien Poland Contest via telephone contact, email contact or by completing the form on the Contest website, the Organizer shall promptly send the Contest Participant the template of the Agreement referred to above together with the payment details regarding the fees indicated in §11 of the Contest Regulations.
- 4.4. Subsequently, the Contest Participant shall send the completed Application Form to the email address indicated by the Organizer.
- 4.5. The Contest Participant should submit the application between 16 March 2026 and 30 September 2026.
- 4.6. In the event of formal deficiencies in the Application Form, the Organizer shall request the Contest Participant to remedy them electronically via the e-mail address indicated by the Contest Participant. The Contest Participant shall be obliged to remedy the formal deficiencies within 3 days from the date of receipt of the request. If the formal deficiencies of the Application Form are not remedied within the time limit specified in the preceding sentence, the application that does not meet the formal requirements shall be rejected, and the Organizer shall promptly inform the Contest Participant thereof by electronic means.
- 4.7. The Organizer shall inform the Contest Participant about the registration of the submission by electronic means in the event of receiving a complete Application Form or after the formal deficiencies have been remedied in the manner and within the time limits specified in sections 4.5–4.6 above.
- 4.8. The submission of a complete Application Form, in accordance with §4 of the Contest Regulations, shall be deemed equivalent to expressing the intention to apply for participation in the Contest.
- 4.9. If the Participant withdraws from participation after signing the Agreement with the Organizer, the Organizer may charge a handling fee equal to 50% of the applicable Contest fee specified in §11 section 11.2.
- 4.10. Submission to the Contest shall be deemed equivalent to the Contest Participant undertaking to provide the Contest Committee with all necessary information and materials confirming the data contained in the Application Form. The Organizer and the Contest Committee undertake to keep confidential the information and materials referred to in this section 4.10.



- 4.11. By submitting the application, the Contest Participant confirms that they have read the Contest Regulations and their appendices and agree to comply with their provisions. The Participant also consents to the processing of their personal data for the purpose of conducting the Contest. Providing personal data is not mandatory; however, it is necessary in order to participate in the Contest. Each Contest Participant has the right to access their processed personal data and the right to request its modification, completion, correction or update in accordance with the Information Clause attached to the Agreement with the Contest Participant.

§5 RESULTS OF THE CONTEST

- 5.1. The results of the Contest will be announced during the Prix Galien Poland 2026 Medal Ceremony (hereinafter referred to as the “Final Gala”), which will take place on 17 November 2026.
- 5.2. Contest Participants who submitted a complete Application Form and participated in the Contest in accordance with §4 section 4.7 of the Contest Regulations will receive two invitations to the Final Gala per application submitted in one Contest Category. Details of participation in the Final Gala will be sent to the email address indicated in the Agreement with the Contest Participant.

§6 AWARD

- 6.1. The award in the Contest is the Prix Galien medal designed by Albert de Jaeger (hereinafter referred to as the “Award”).
- 6.2. The Contest Laureate may not request the Award to be exchanged for another prize or for any monetary equivalent.
- 6.3. The Award is granted to the Laureate or Laureates in each Contest Category, provided that the Committee may decide not to grant the Award in a given Contest Category. The absence of an award does not create any claim on the part of the Contest Participants.



- 6.4. The Organizer provides for the possibility of granting more than one Award in a given Contest Category.
- 6.5. The Organizer may also grant additional distinctions titled “Pro Bono Humanum” and “Lifetime Achievement Award”, in accordance with §9 below.

§7 CONTEST CATEGORIES

- 7.1. The Award is granted by the Contest Committee in the following categories (hereinafter referred to as the “Contest Categories”):

- 7.1.1. ***Best Innovative Pharmaceutical Product:***

This category is dedicated to innovative medicinal products authorized for marketing in the territory of Poland from 1 January 2021 until the closing date for the submission of Application Forms referred to in section 4.5 above, whose innovation may have a breakthrough impact on the diagnosis, treatment or prevention of diseases.

- 7.1.2. ***Best Innovative Biotechnological Product:***

This category is dedicated to innovative vaccines, ATMPs – products based on cells, tissues or genetic modifications, recombinant proteins and monoclonal antibodies, authorized for marketing in the territory of Poland from 1 January 2021 until the closing date for the submission of Application Forms referred to in section 4.5 above.

- 7.1.3. ***Best Innovative Drug for Rare / Orphan Diseases:***

This category is dedicated to innovative medicinal products intended for the treatment of rare diseases whose innovation may have a breakthrough impact on addressing public health needs, authorized for marketing in the territory of Poland from 1 January 2021 until the closing date for the submission of Application Forms referred to in section 4.5 above.



7.1.4. *Best Innovative Second-Generation Product:*

This category is dedicated to innovative generic or second-generation products authorized for marketing in the territory of Poland from 1 January 2021 until the closing date for the submission of Application Forms referred to in section 4.5 above. These products are characterized by innovations such as a modified drug formulation, a new method of administration, a change in pharmaceutical form or a change in the route of administration, which may improve treatment effectiveness or address public health needs. These products constitute a new therapeutic alternative compared with earlier versions of generic medicines.

7.1.5. *Best Innovative Medical Technology:*

This category is dedicated to innovative medical technologies, including instruments, apparatus, devices and materials used for diagnostic and/or therapeutic purposes, available in the territory of Poland and having undergone the appropriate conformity assessment procedures between 1 January 2021 and the closing date for the submission of Application Forms referred to in section 4.5 above. The category includes hardware solutions and medical devices in which the key carrier of innovation is material technology supporting diagnosis, treatment or monitoring of patients' health. Software may constitute an element of a medical technology provided that it forms an integral part of a device or hardware-based system.

7.1.6. *Best Innovative Digital Health Solution:*

This category is dedicated to innovative digital solutions in healthcare, including software applications, data-driven systems, algorithms, artificial intelligence and other digital systems supporting diagnosis, therapy, patient health monitoring and the management of healthcare or clinical processes. Solutions eligible for submission in this category must be available in the territory of Poland in the period from 1 January 2021 until the closing date for the submission of Application Forms referred to in section 4.5 above.

7.1.7. *Best Innovative Medical Research:*

This category is dedicated to research projects conducted in the territory of Poland, in particular early-phase clinical studies (Phase I–II), aimed at



developing innovative solutions addressing the challenges of modern medicine in a breakthrough manner. Projects that are ongoing or completed in 2026 may be submitted. The purpose of this category is to recognize the quality and innovation potential created by companies and scientific institutions, to emphasize the role of scientific research as a mechanism strengthening the national biomedical sector, and to promote Poland as a place where breakthrough discoveries addressing key health needs can be developed.

7.1.8. *Best Innovative Startup:*

This category is dedicated to innovative startups and young companies operating across all areas of healthcare, including those applying modern technologies in prevention, diagnostics, treatment or healthcare management. Entities that began operations in the territory of Poland between 1 January 2018 and the closing date for the submission of Application Forms referred to in section 4.5 above may apply, as well as companies established before 2018 that have recently undergone a significant transformation involving a change in business profile and the launch of activities in the area of medical innovation or health technologies. The innovation of the submitted projects should have the potential to create a breakthrough impact on addressing public health needs.

- 7.2. Detailed requirements concerning the above-mentioned Contest Categories are specified in Appendix No. 1 to the Contest Regulations.

§8

CONTEST COMMITTEE

- 8.1. The Contest Committee operates, evaluates and makes decisions by voting in accordance with the rules set out in the Committee Rules of Procedure.
- 8.2. The Contest Committee evaluates the submissions of Contest Participants on the basis of complete and correctly submitted Application Forms, in accordance with the guidelines specified in §4 of the Contest Regulations.



- 8.3. The Committee Rules of Procedure include provisions relating to potential conflicts of interest of the Members of the Contest Committee.

§9

ORGANIZER'S AWARDS

- 9.1. The Galien Foundation, in cooperation with the Organizer, reserves the right to grant, at its sole discretion and outside the Contest Categories, the “Pro Bono Humanum” Award (hereinafter referred to as the “Pro Bono Humanum Award”) and the “Lifetime Achievement” Award (hereinafter referred to as the “Lifetime Achievement Award”).
- 9.2. The Pro Bono Humanum Award may be granted to a selected entity / organization or individual / individuals who have made a significant contribution to improving the well-being of humanity through social, humanitarian or scientific activities.
- 9.3. The Lifetime Achievement Award may be granted to an individual whose long-standing professional activity in the field of biomedical sciences, medicine or public health has had exceptional importance for the development of these disciplines and has had a lasting impact on improving the quality of life of patients and society.
- 9.4. The Pro Bono Humanum Award and the Lifetime Achievement Award are honorary distinctions granted by the Galien Foundation, independent of the Contest process and the requirements of the Contest Categories.

§10

PATRONS AND SPONSORS OF THE CONTEST

- 10.1. Patrons, partners and sponsors of the Contest may include natural persons, legal persons or organizational units without legal personality that are granted legal capacity under applicable law and with whom the Organizer has concluded separate agreements.



§11 FEES

- 11.1. In order to submit participation in the Contest, in accordance with §4 of the Contest Regulations, the Contest Participant shall pay the applicable Contest fee or fees.
- 11.2. The amount of the Contest fee for one submission by a Contest Participant in a specific (single) Contest Category is as follows:
- (a) or one submission in Contest Categories 7.1.1–7.1.7: PLN 15,000 net if the submission is made by 30 April 2026;
 - (b) for one submission in Contest Categories 7.1.1–7.1.7: PLN 20,000 net if the submission is made after 30 April 2026;
 - (c) in the case of a submission in Contest Category 7.1.8 (“Best Innovative Startup”) by 30 April 2026, the Contest fee amounts to 50% of the amount specified in section 11.2(a);
 - (d) in the case of a submission in Contest Category 7.1.8 (“Best Innovative Startup”) after 30 April 2026, the Contest fee amounts to 50% of the amount specified in section 11.2(b);
 - (e) in the case of a submission in Contest Categories 7.1.1–7.1.7 as a “Re-submission”, i.e. a repeated submission of a product, technology or solution that had been submitted in the Prix Galien Poland 2025 edition but did not receive the title of Laureate in the given Contest Category, the submission fee amounts to PLN 10,000 net;
 - (f) in the case of a submission in Contest Category 7.1.8 (“Best Innovative Startup”) as a “Re-submission”, i.e. a repeated submission of a startup that had been submitted in the Prix Galien Poland 2025 edition but did not receive the title of Laureate in that Contest Category, the submission fee amounts to PLN 5,000 net

(hereinafter referred to as the “Contest Fees”).



- 11.3. The above fees do not include the applicable value-added tax. In accordance with applicable regulations, the total amount of the fee, depending on the number of submissions made by the Contest Participant in one or more Contest Categories, shall be increased by value-added tax at the applicable rate.
- 11.4. The fee resulting from the number of submissions made by the Contest Participant and the amounts specified in section 11.2 shall be paid within the time limit and in accordance with the terms specified in the Agreement with the Contest Participant, pursuant to §4 section 4.3 of the Contest Regulations.
- 11.5. The Organizer reserves the right to change the amount of the Contest Fees.

§12 RIGHTS OF THE ORGANIZER

- 12.1. The Organizer reserves that it shall not be liable for events preventing the Contest from being conducted or properly conducted if such events could not have been foreseen or prevented by the Organizer. In the event of circumstances preventing the Contest from being conducted, the Organizer shall promptly inform the Contest Participants electronically via the email address indicated in the Agreement with the Contest Participant.
- 12.2. The Organizer reserves the right to cancel the Contest, of which the Contest Participants shall be promptly informed electronically via the email address indicated in the Agreement with the Contest Participant.
- 12.3. The Organizer reserves the right to change the date of the Contest results announcement or to change the form of the Contest (including the Final Gala), of which the Contest Participants shall be promptly informed electronically via the email address indicated in the Agreement with the Contest Participant.
- 12.4. The Organizer reserves that the information provided in connection with the Contest, during and after its completion, does not constitute advertising of any medicinal product or medical device within the meaning of applicable law. The purpose of the Contest is to promote innovation in medicine and/or pharmacy, including encouraging scientific research and the development of new



technologies, and not to advertise any medicinal product or medical device. The content and form of all materials concerning medicinal products and medical devices, as well as the manner of their presentation, shall be determined solely by the Contest Participants.

§13 FINAL PROVISIONS

- 13.1. Contest Laureates who have been granted the Award have the right to freely use the designation “Prix Galien Poland 2026 Award” and “Prix Galien Poland 2026 Winner” in all promotional materials, in accordance with applicable regulations, subject to the Organizer’s trademark rights in this respect.
- 13.2. During the Contest, the Organizer, its employees and representatives:
 - (a) shall not offer, make, promise, authorize or accept any payments or provide any financial or non-financial benefits, directly or indirectly, to public officials, administrative authorities or any other persons for the purpose of influencing, inducing or rewarding any action, omission or decision in order to secure an undue advantage or obtain or retain a source of revenue;
 - (b) shall comply with all applicable local and international laws and regulations on anti-bribery and anti-corruption. The Organizer ensures that its employees and representatives comply with and will continue to comply with all requirements concerning adherence to applicable anti-bribery and anti-corruption regulations.
- 13.3. The Organizer reserves the right to amend the provisions of these Contest Regulations. Any amendments to the Contest Regulations must be made in writing and shall enter into force upon publication of the updated version on the website www.prixgalienpolska.com.
- 13.4. The Contest is not subject to the provisions of the Act of 19 November 2009 on Gambling Games (Journal of Laws of 2023, item 227).



13.5. Contact details of the Organizer: Foundation for Innovation in Medicine and Pharmacy, Platinum Business Park, ul. Domaniewska 44, 02-672 Warsaw, tel.: +48 (22) 26 62 785, e-mail: fundacja@prixgaliencee.com

Appendices:

Appendix No. 1:

Guidelines regarding submission and application documentation.

Appendix No. 2:

Template of the Contact Form available on the website www.prixgalienpolska.com.



Appendix No. 1 to the Contest Regulations

GUIDELINES FOR SUBMISSION AND APPLICATION DOCUMENTATION IN THE PRIX GALIEN POLAND 2026 CONTEST

1. STAGES OF SUBMISSION TO THE “PRIX GALIEN POLAND 2026” CONTEST

1.1. The Contest Participant expresses their intention to participate in the Prix Galien Poland Contest by contacting the Organizer by telephone, email or by completing the Contact Form available on the website www.prixgalienpolska.com. The template of the above-mentioned Contact Form constitutes Appendix No. 2 to the Contest Regulations.

1.2. Subsequently, the Organizer sends the Contest Participant, via the email address indicated by the Contest Participant, the template of the Agreement referred to in §4 section 4.2(a) of the Contest Regulations, together with the necessary payment details regarding the fee or fees specified in §11 of the Contest Regulations.

1.3. The Contest Participant submits the application to the Prix Galien Poland 2026 Contest by correctly completing and signing the Application Form consisting of the following documents:

- (a) Confirmation of payment of the required fee or fees specified in §11 of the Contest Regulations; Potwierdzenia uiszczenia wymaganej opłaty lub opłat wskazanych w §11 Regulaminu Konkursu;
- (b) Application Documentation appropriate for the Contest Category or Categories selected by the Contest Participant, as described in detail in this Appendix (Application Documentation does not require a signature).

The Application Form together with its attachments should be submitted to the Organizer at the indicated email address in accordance with the Contest Regulations. The Application Form will be confirmed by registration of the submission in accordance with the rules specified in the Contest Regulations.



2. DEADLINES

- 2.1. In the case of submission to the Contest by 30 April 2026, eligibility to participate in the Contest with the preferential Contest Fee amount is guaranteed provided that the Agreement is signed and payment is made by that date, i.e. by 30 April 2026. The Application Documentation may be submitted at a later date, however no later than the closing date for submission of Application Forms referred to in section 4.5 of the Contest Regulations.
- 2.2. In the event that the Contest Participant submits participation in the Contest after 30 April 2026, eligibility to participate in the Contest is guaranteed provided that the Agreement is signed and payment is made no later than the closing date for submission of Application Forms referred to in section 4.5 of the Contest Regulations. The Contest Participant who has signed the Agreement and made the payment for the submission shall submit the Application Documentation no later than the closing date for submission of Application Forms referred to in section 4.5 of the Contest Regulations.

3. GUIDELINES FOR PREPARING APPLICATION DOCUMENTATION

3.1. EDITORIAL GUIDELINES

- 3.1.1. The Application Documentation should be prepared in the Polish.
- 3.1.2. The Contest Participant submits the Application Documentation in digital form (PDF) to the email address indicated by the Organizer.
- 3.1.3. Font: Arial, 11 points, line spacing 1.0, A4 format.
- 3.1.4. The Application Documentation may not exceed 5 pages of text. It is possible to include graphics, tables and other visual materials, provided that the entire Application Documentation, including text and additional materials, does not exceed a total of 7 pages.



3.2. SUBSTANTIVE GUIDELINES IN INDIVIDUAL CATEGORIES

3.2.1. Category: **Best Innovative Pharmaceutical Product**

- 3.2.1.1. The category is dedicated to innovative medicinal products authorized for marketing in the territory of Poland from 1 January 2021 until the closing date for submission of Application Forms referred to in section 4.5 of the Contest Regulations, in accordance with applicable legal provisions. The submission may also concern a new or innovative indication added during the above-mentioned period.
- 3.2.1.2. The Organizer accepts submissions for individual products and not for classes of products.
- 3.2.1.3. The Contest Participant submitting the product holds the rights to the name and trademark of the submitted product.
- 3.2.1.4. The Application Documentation should include:
 - (I) description of the product;
 - (II) information on the innovation and effectiveness of the product supported by research;
 - (III) description of the impact of the product on improving patients' quality of life and comfort;
 - (IV) comparison with the "Gold Standard";
 - (V) bibliography including the most important publications (minimum 3 publications);
 - (VI) a list explaining the abbreviations used in the submission; justification for the submission.

3.2.2. Category: **Best Innovative Biotechnological Product**

- 3.2.2.1. The category is dedicated to innovative vaccines, ATMPs – products based on cells, tissues or genetic modifications, recombinant proteins and monoclonal antibodies authorized for marketing in Poland in accordance with applicable regulations from 1 January 2021 until the closing date for submission of Application Forms referred to in section 4.5 of the Contest Regulations. The submission may also concern a new or innovative indication added during the above-mentioned period.



- 3.2.2.2. The Organizer accepts submissions for individual products and not for classes of products.
- 3.2.2.3. The Contest Participant submitting the product holds the rights to the name and trademark of the submitted product.
- 3.2.2.4. The Application Documentation should include:
 - (I) description of the product;
 - (II) information on the innovation and effectiveness of the product supported by research;
 - (III) description of the impact of the product on improving patients' quality of life and comfort;
 - (IV) comparison with the "Gold Standard";
 - (V) bibliography including the most important publications (minimum 3 publications);
 - (VI) a list explaining the abbreviations used in the submission;
 - (VII) justification for the submission.

3.2.3. Category: **Best Innovative Drug for Rare / Orphan Diseases**

- 3.2.3.1. The category is dedicated to innovative medicinal products intended for the treatment of rare diseases whose innovation may have a breakthrough impact on addressing public health needs, authorized for marketing in Poland in accordance with applicable regulations from 1 January 2021 until the closing date for submission of Application Forms referred to in section 4.5 of the Contest Regulations. The submission may also concern a new or innovative indication added during the above-mentioned period.
- 3.2.3.2. The Organizer accepts submissions for individual products and not for classes of products.
- 3.2.3.3. The Contest Participant submitting the product holds the rights to the name and trademark of the submitted product.
- 3.2.3.4. The Application Documentation should include:
 - (I) description of the product;
 - (II) information on the innovation and effectiveness of the product supported by research;
 - (III) description of the impact of the product on improving patients' quality of life and comfort;
 - (IV) comparison with the "Gold Standard";



- (V) bibliography including the most important publications (minimum 3 publications);
- (VI) a list explaining the abbreviations used in the submission;
- (VII) justification for the submission.

3.2.4. Category: ***Best Innovative Second-Generation Product***

- 3.2.4.1. This category is dedicated to innovative generic or second-generation products authorized for marketing in the territory of Poland from 1 January 2021 until the closing date for submission of Application Forms referred to in section 4.5 above, and characterized by innovations such as a modified drug formulation, a new method of administration, a change in pharmaceutical form or a change in the route of administration, which may improve treatment effectiveness or address public health needs. These products constitute a new therapeutic alternative compared with earlier versions of generic medicines.
- 3.2.4.2. The Organizer accepts submissions for individual products and not for classes of products.
- 3.2.4.3. The Contest Participant submitting the product holds the rights to the name and trademark of the submitted product.
- 3.2.4.4. The Application Documentation should include:
 - (I) description of the product;
 - (II) information on the innovation and effectiveness of the product supported by research;
 - (III) description of the impact of the product on improving patients' quality of life and comfort;
 - (IV) comparison with the "Gold Standard";
 - (V) bibliography including the most important publications (minimum 3 publications);
 - (VI) a list explaining the abbreviations used in the submission;
 - (VII) justification for the submission.



3.2.5. Category: **Best Innovative Medical Technology**

- 3.2.5.1. This category is dedicated to innovative medical technologies, including instruments, apparatus, devices and materials used for diagnostic and/or therapeutic purposes, available in the territory of Poland and having undergone the appropriate conformity assessment procedures between 1 January 2021 and the closing date for submission of Application Forms referred to in section 4.5 of the Contest Regulations. The category includes hardware solutions and medical devices in which the key carrier of innovation is material technology supporting diagnosis, treatment or monitoring of patients' health. Software may constitute an element of a medical technology provided that it forms an integral part of a device or hardware-based system.
- 3.2.5.2. The Contest Participant submitting the technology holds the rights to the name and trademark of the submitted medical technology.
- 3.2.5.3. The Application Documentation should include:
- (I) description of the medical technology;
 - (II) information on the innovation and effectiveness of the technology supported by research;
 - (III) description of the impact of the technology on improving patients' quality of life and comfort;
 - (IV) comparison with the "Gold Standard" (if applicable);
 - (V) bibliography including the most important publications (minimum 3 publications);
 - (VI) a list explaining the abbreviations used in the submission;
 - (VII) justification for the submission.

3.2.6. Category: **Best Innovative Digital Health Solution**

- 3.2.6.1. This category is dedicated to innovative digital solutions in healthcare based on data, software, algorithms, artificial intelligence or digital systems supporting diagnosis, therapy, healthcare management or clinical processes. Solutions eligible for submission in this category must be available in the territory of Poland and must have been implemented or made available to users between 1 January 2021 and the closing date for



submission of Application Forms referred to in section 4.5 of the Contest Regulations.

- 3.2.6.2. The Contest Participant submitting the solution holds the rights to the name and trademark of the submitted solution.
- 3.2.6.3. The Application Documentation should include:
 - (I) description of the digital solution;
 - (II) information on the innovation and effectiveness of the solution supported by research or data analysis;
 - (III) description of the impact of the solution on improving healthcare quality, clinical processes or patient comfort;
 - (IV) comparison with the “Gold Standard” (if applicable);
 - (V) bibliography including the most important publications (minimum 3 publications);
 - (VI) a list explaining the abbreviations used in the submission;
 - (VII) justification for the submission.

3.2.7. Category: **Best Innovative Medical Research**

- 3.2.7.1. This category is dedicated to research projects conducted in the territory of Poland, in particular early-phase clinical studies (Phase I–II), aimed at developing innovative solutions addressing the challenges of modern medicine in a breakthrough manner. Projects that are ongoing or completed in 2026 may be submitted.
- 3.2.7.2. The purpose of this category is to recognize the quality and innovation potential created by companies and scientific institutions, to emphasize the role of scientific research as a mechanism strengthening the national biomedical sector and to promote Poland as a place where breakthrough discoveries addressing key health needs can be developed.
- 3.2.7.3. The Organizer accepts submissions for individual research projects.
- 3.2.7.4. The Application Documentation should include:
 - (I) description of the research concept, including the scientific background of the project, the uniqueness or innovation of the proposed solution, in particular with regard to the molecular mechanism of action of the product, its delivery method or an innovative



combination of products, as well as available preliminary results confirming the potential of the product and the level of advancement of the research;

- (II) description of the clinical significance, including the epidemiological background and the social importance of the health problem, including with reference to rare diseases or populations with limited access to therapies, identification of available therapeutic alternatives and expected health outcomes, as well as identification of research centers in Poland involved in the study together with a description of their role;
- (III) description of the translational potential, including the current stage of development of the research work, the plan for further development of the project, including the role of the entity conducting the research, assumptions regarding the implementation of the research results within the entity's own activities or in cooperation with third parties, as well as identification of possible competing solutions and potential barriers to implementation;
- (IV) information on the clinical trial status, including the trial number in the CTIS system or ClinicalTrials.gov, in the case of initiated clinical trials;
- (V) in the case of projects for which a clinical trial has not yet been initiated – a copy of the positive opinion of the competent bioethics committee regarding the implementation of the project;
- (VI) a list of research centers where the studies are being conducted or planned to be conducted;
- (VII) justification for the submission.

3.2.8. Category: **Best Innovative Startup**

- 3.2.8.1. This category includes innovative startups operating across all areas of healthcare that began operations in the territory of Poland between 1 January 2018 and the closing date for submission of Application Forms referred to in section 4.5 of the Contest Regulations, or were registered earlier but have recently



undergone a significant transformation and started activities in the field of medical innovation. A startup may be either a formally registered company or an entity operating in another organizational form, such as a research and development project, a team in the incubation phase or an unregistered initiative. The innovation of these entities should have the potential to create a breakthrough impact on addressing public health needs.

- 3.2.8.2. The Contest Participant submitting the startup holds the rights to the name and trademark of the startup (if applicable).
- 3.2.8.3. The Application Documentation should include:
 - (I) description of the startup;
 - (II) information on the innovation of the activities conducted;
 - (III) description of the impact of the solution on the patient or the healthcare system (diagnosis, treatment, prevention, management);
 - (IV) comparison with the “Gold Standard” (if applicable);
 - (V) composition of the management team;
 - (VI) a list explaining the abbreviations used in the submission;
 - (VII) justification for the submission.



Appendix No. 2 to the Contest Regulations

TEMPLATE OF THE CONTACT FORM AVAILABLE ON THE WEBSITE

www.prixgalienpolska.com:

Zgłoszenia do konkursu Prix Galien Polska

Prosimy o wypełnienie formularza. Na przesłany adres email wyślemy komplet dokumentów niezbędnych do dokonania zgłoszenia Państwa innowacji. Alternatywnie, prosimy o kontakt pod numerem telefonu lub adresem email, który znajdziecie Państwo poniżej.

Informacje podstawowe

≡ MENU

W jakiej kategorii chcesz zgłosić innowację?



Jak brzmi nazwa innowacji?

Twoje dane kontaktowe

Imię *

Nazwisko *

Jaką firmę bądź instytucję reprezentujesz?

Stanowisko

Telefon

Email *

WYŚLIJ