

AI in Health Coalition

Leader: Ligia Kornowska

phone: +48 690 875 075

email: biuro@aiwzdrowiu.pl

website: www.aiwzdrowiu.pl



TERMS & CONDITIONS OF THE AI IN HEALTH COALITION

(„Terms & Conditions”)

1. GENERAL PROVISIONS

- 1.1. The regulations define **the basic principles of the AI in Health Coalition** (hereinafter referred to as the "Coalition"), including the principles of joining the Coalition, the principles of membership in the Coalition and the principles of operation of the Coalition.
- 1.2. The coalition was established and operates as a **voluntary agreement of its members**.
- 1.3. Coalition members undertake **actions together in accordance with the goals and values expressed in the Manifesto of the AI in Health Coalition**. The text of the Manifesto of the AI in Health Coalition is attached in the 1st Appendix to the Regulations.
- 1.4. The activities of the Coalition are coordinated by Ligia Kornowska, running a business under the name "Medexpert Ligia Kornowska" with its registered office in Warsaw, ul. Żelazna 59 lok. 1405, 00-848 Warsaw, entered into the Central Register and Information on Economic Activity of the Republic of Poland kept by the minister competent for economy, NIP: 5272863628, REGON: 381172361 (hereinafter: "Coalition Leader").
- 1.5. The strategic legal partner of the Coalition and at the same time the main member is the **Domański Zakrzewski Palinka Law Firm**.
- 1.6. The administrator of personal data of members of the Coalition, and persons acting on their behalf is the Coalition Leader. The model of the information obligation clause is attached in the 3rd Appendix to the Regulations.
- 1.7. **The official website dedicated** to the Coalition is www.aiwzdrowiu.pl

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2. JOINING THE COALITION

- 2.1. The coalition remains open to all entities ready to **actively support the activities indicated in the Manifesto of the AI in Health Coalition.**
- 2.2. **Any private and legal entities may join the Coalition**, in particular private entities with expert knowledge in the field of health protection and new technologies, as well as entrepreneurs operating in the healthcare market and technology companies.
- 2.3. The coalition consists of **main members** and **supporting members**
- 2.4. The condition for joining the Coalition is submitting as a **declaration of will to join the Coalition, indicating the type of membership that the entity is applying for (2nd Appendix), which is recognized as acceptance of the Regulations and the Manifesto of the AI in Health Coalition (1st Appendix).** The declaration of will referred to in the above sentence should be submitted in writing, electronically or as a document to the following e-mail address: **biuro@aiwzdrowiu.pl**, by a person (or persons) duly authorized to represent the applicant's entity.
- 2.5. **The status of the main member of the Coalition** may be obtained by an entity which additionally meets one of the following conditions:
 - 2.5.1. the member's e-mail address was placed on Coalition member's mailing list before January 31, 2021 or
 - 2.5.2. member has been recommended by at least 2 main members of the Coalition and the Coalition Leader
and indicated in the declaration of will to join the type of membership for which he is applying (2nd Appendix).
- 2.6. **Joining the Coalition** is final after receiving an **electronic confirmation** from the Coalition Leader about being accepted as a member of the Coalition.
- 2.7. The Coalition Leader may refuse the applicant if the applicant's activity profile does not correspond to the Coalition's scope of activities or is inconsistent with the Coalition's objective, or if there are justified premises indicating that the applicant's membership status may have a negative impact on the Coalition's reputation.
- 2.8. The Coalition Leader **may refuse to grant the status of the main member of the Coalition in the event of failure to meet the requirements specified in point 2.5.**

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2.9. Information about the submission of the Manifesto of the AI in Health Coalition or about admission of members to Coalition **may be publicly published**, in particular on the Coalition's website and on the official profiles of the Coalition in social media.

3. RULES OF MEMBERSHIP

3.1. **Membership in the Coalition does not oblige to pay any fees**, in particular membership fees.

3.2. **Each member of the Coalition can and should actively participate in meetings and events** organized by the Coalition as well as in its projects and **act to support the Coalition's goals**. A member of the Coalition should act in an ethical and transparent manner, respecting good manners and legal regulations, caring for the good name of the Coalition and members of the Coalition.

3.3. A supporting member of the Coalition is entitled to:

- a. use in public the title of a supporting member and use verbal and graphic markings in accordance with point 7 of the Regulations;
- b. obtain information addressed to supporting members in a separate mailing group;
- c. formulating remarks and comments to the Coalition's Positions presented for wider consultations by the Coalition Leader;
- d. participate in events and meetings organized by the Coalition, on the terms presented by the Coalition Leader;
- e. financial or substantive participation in the implementation of the Projects indicated in the point 5 of the Regulations, on the terms specified by the Coalition Leader or the Project initiator in consultation with the Coalition Leader;
- f. participate in working groups indicated in point 12 of the Regulations on the terms specified by the Coalition Leader or the project initiator in consultation with the Coalition Leader, in particular in the regulations of the working groups;
- g. taking other actions resulting from the Regulations.

3.4. A main member of the Coalition is entitled to:

- a. use in public the title of the main member and use verbal and graphic signs in accordance with point 7 of the Regulations;

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- b. obtaining information addressed to the main members in a separate mailing group;
- c. formulating remarks and comments to all Coalition Positions and voting on the Positions in accordance with point 10 of the Regulations;
- d. presenting conclusions and proposals for the Coalition's activities;
- e. preferential participation in events and meetings, including events and meetings with key stakeholders of the Coalition on the terms presented by the Coalition Leader;
- f. identification of Projects and financial or substantive participation in the implementation of the Projects referred to in point 5 of the Regulations on the terms specified by the Coalition Leader;
- g. initiating the work of the working groups indicated in point 12 of the Regulations and participation in working groups on the terms specified by the Coalition Leader, in particular in the regulations of the working groups;
- h. taking other actions resulting from the Regulations.

3.5. **A member of the Coalition may resign from membership at any time** by submitting a declaration of resignation from membership to the Coalition Leader to the address biuro@aiwzdrowiu.pl, on which he should indicate the date, i.e., the day of resignation from membership in the Coalition.

3.6. The Coalition Leader is obliged, within 14 days from the resignation of a Coalition member, to remove all information about the member from the Coalition's website and official profiles of the Coalition in social media, unless removal, in particular for technical reasons, is not possible.

3.7. A member of the Coalition who violates the rules of the Regulations **may be excluded from the Coalition by the Coalition Leader.**

4. COALITION LEADER

4.1. **The Coalition Leader is obliged to perform his duties with the utmost due diligence**, respecting all members of the Coalition and their interests, act in accordance with generally applicable laws, promote ethical behavior among Coalition members, caring for the good name of the Coalition and its members. The Coalition Leader will carry out, in particular, the following activities:

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- a. promote the Coalition's goal and actively participate in its implementation;
 - b. define the directions of the Coalition's activity and development;
 - c. propose initiatives that are consistent with the goal of the Coalition;
 - d. negotiate, conclude and terminate agreements with the Coalition's stakeholders;
 - e. stimulate the activity of the Coalition, including maintaining the Coalition's website, organizing and chairing meetings and meetings of Coalition members, conferences and symposia on behalf of and for the Coalition;
 - f. ensure coherent operation of the Coalition, in particular in connection with the implementation of Projects and the issuance of Positions;
 - g. convene Coalition meetings;
 - h. determine the content of the Regulations and the regulations of the working groups;
 - i. disseminate the application of good practices in the field of artificial intelligence in the medical sector;
 - j. undertake cooperation with Polish and foreign institutions and organizations operating in the scope consistent with the Coalition's goal;
 - k. verify the applications of potential members of the Coalition;
 - l. keep a register of Coalition members.
- 4.2. The Coalition Leader is entitled to give the Coalition's honorary patronage to a specific project or event, as long as it is consistent with the Coalition's goal.

The Leader informs the main members of the Coalition about the intention to give patronage at least 3 (three) days prior the date of giving the patronage, along with the justification. If an objection is raised within 3 (three) days by at least two main members of the Coalition, the Coalition Leader immediately orders a vote on the matter in question. To voting on giving patronage, the provisions regarding the acceptance of Positions shall apply accordingly.

5. PROJECTS REALIZATION

The Coalition may implement projects consistent with the Coalition's goal but going beyond the current functioning of the Coalition ("Project"). The Leader informs the main members of the intention to implement the Project at least 7 days before the

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date of commencement of the Project implementation, together with the justification. If at least two main members of the Coalition raise an objection within 7 days, the Coalition Leader immediately orders a vote on the matter in question. To voting for the implementation of the Project, the provisions regarding the acceptance of Positions shall apply accordingly.

6. PROJECTS FINANCING

Projects implemented by the Coalition may involve the collection of voluntary contributions from members. Members who pay a contribution may be entitled to additional benefits under the Project.

7. DISTINCTIVE SIGNS

- 7.1. Coalition members are entitled to use the designation (verbal, verbal-graphic, graphic) of the Coalition solely for the purpose of informing about their membership in the Coalition and the form of membership. The remaining use of the Coalition's graphic designation requires the consent of the Coalition Leader, at least in the form of a document, each time.
- 7.2. The Coalition Leader may use the designation (verbal, verbal-graphic, graphic) identifying a Coalition member, on the Coalition's website and on the official Coalition profiles in social media in sections concerning Coalition members, unless the member provides the Coalition Leader with other terms of using the designation. The use of a designation (verbal, verbal-graphic, graphic) identifying a Coalition member in the remaining scope requires consent on the terms indicated by the member.

8. NEWSLETTER

- 8.1. Each visitor to the domain **www.aiwzdrowiu.pl** may consent to receive the Coalition's newsletter at the e-mail address provided ("Newsletter"). The consent to receive the Newsletter takes place by selecting the appropriate consent on the website www.aiwzdrowiu.pl in the Newsletter form. The Newsletter Regulations are available at www.aiwzdrowiu.pl.
- 8.2. Receiving the Newsletter is voluntary, free of charge and can be unsubscribed at any time, it is also independent from obtaining the status of a Coalition member, however, each Coalition member is added to the Newsletter, from which he can unsubscribe at any time.

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9. COMUNICATION

All correspondence, including any questions regarding the Coalition's activities, should be sent to the following e-mail address: biuro@aiwzdrowiu.pl or placed by a phone call to the following number: +48 690 875 075.

10. MEETINGS AND POSITIONS OF THE COALITION - VOTING

10.1. The Coalition may present positions, opinions, recommendations or good practices on issues related to artificial intelligence in the medical sector ("Position").

10.2. Decisions as to the direction and content of the Position:

- a) are held at Coalition meetings convened by the Coalition Leader or
- b) in circulation mode

in the form of a resolution, in open voting, if all main members have been duly invited or informed by sending information to the e-mail address for correspondence.

10.3. **Only the main members of the Coalition and the Coalition Leader participate in meetings of the Coalition regarding the determination of the Position.** Meetings may be held stationary or using means of remote communication. Each Coalition member and Coalition Leader has one vote. Resolutions are adopted by a simple majority of votes cast. In the event of an equal number of votes "for" and "against" when adopting a resolution, the deciding vote belongs to the Coalition Leader.

10.4. **Meetings of the Coalition on the determination of the Position are convened by prior notification sent in electronic form to the contact e-mail address of the main member of the Coalition, containing information about the date, time, place (exact address), agenda, at least seven days before the meeting. In urgent cases, when it is in the interest of the Coalition, the notification referred to in the preceding sentence may be provided, in accordance with the requirements as to the form, at least one day before the meeting. Prior to the Meeting, the Coalition Leader sends a position proposal.**

10.5. The leader of the Coalition may order the adoption of resolutions by circulation, in particular by means of direct remote communication without the need to convene a meeting, with the provisions of items 10.3 and 10.4. apply accordingly.

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- 10.6. Adopting resolutions by means of direct remote communication takes place in accordance with the order of the Coalition Leader:
- a) **during the meeting:** by using a telephone or any other telecommunication device enabling all principal members to hear each other or otherwise convey their statements. The main member's failure to participate in the teleconference mode shall be considered a resignation from voting, or
 - b) **by circulation:** by sending draft resolutions to the e-mail address of the main members of the Coalition and setting a deadline for voting, by sending an appropriate e-mail to the Coalition Leader's e-mail address. Failure to vote in the above manner within the time limit specified in the Coalition Leader's order means no participation in the vote.
- 10.7. A Coalition meeting to establish a Position and other Coalition meetings may be held without being formally convened, provided that all the main members of the Coalition and the Coalition Leader agree to hold the meeting and the proposed agenda.
- 10.8. Written protocols are made from the Coalition meetings, including the content of the adopted resolutions. Protocols from the Coalition meetings are kept by the Coalition Leader.
- 10.9. Meetings of the Coalition on the determination of the Position and on other matters are convened by the Coalition Leader according to the current needs resulting from the activities of the Coalition.

11. COALITION REPRESENTATION

- 11.1. **The Coalition Leader is authorized to make statements on behalf of the Coalition** and to represent the Coalition.
- 11.2. The Coalition Leader may authorize one of the Coalition members or a third party to represent the Coalition. Authorization to represent the Coalition requires a written power of attorney.

12. WORKING GROUPS

- 12.1. Depending on the needs, **the Coalition Leader, on his own initiative or on the initiative of at least 3 main members of the Coalition, may decide to establish working groups in order to implement specific projects or tasks** important from the point of view of the Coalition's goals and means of their implementation.

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12.2. The Coalition Leader coordinates the work of the working groups and may establish the regulations of the working groups in consultation with the originators of the working groups.

13. FINAL PROVISIONS

13.1. In the event of a change to the Regulations, the Coalition Leader sends its new version at least 14 days before the effective date to the members' e-mail address provided for contact, together with the justification for the changes. If at least two main members of the Coalition raise an objection within 7 days, the Coalition Leader immediately orders a vote on the matter in question. The provisions concerning the acceptance of Positions shall apply accordingly to voting to amend the Regulations.

13.2. If the amended Regulations are not accepted, a member of the Coalition may resign from membership with immediate effect by sending a relevant information to the e-mail address biuro@aiwzdrowiu.pl.

13.3. In the event that the amendments to the Regulations are of a technical or editorial nature, it is not necessary to maintain the minimum period of 14 days referred to in the previous paragraph.

13.4. Attachments are an integral part of the Regulations.

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1st Appendix – Manifesto of the AI in Health Coalition

„Artificial Intelligence should work for people and the society”¹

MANIFESTO OF THE AI IN HEALTH COALITION

We, the undersigned, signatories to this Manifesto

IDENTIFYING solutions based on artificial intelligence as one of the greatest technological breakthroughs of our time²;

RECOGNIZING the importance of the benefits associated with the proper use of artificial intelligence in health care³;

OBSERVING the growing influence of artificial intelligence on the health sector;

NOTING the existing barriers to development in this area, which are of a different nature, e.g. awareness, financial, legal;

HAVING the knowledge, skills and experience in the field of AI solutions;

WANTING to participate in the shaping and implementation of the AI development strategy in the health sector;

WISHING for the Coalition to be an effective tool for the AI development strategy in the health sector;

We declare the following:

- (1) we want to create a joint representation of stakeholders participating in the health care system, which will be a partner for public entities and other entities important from the point of view of the development and implementation of artificial intelligence in health;
- (2) we want to support the development of artificial intelligence tools in the health care system in order to fully use their potential as a way to improve efficiency, quality and the availability of healthcare services and the functioning of the healthcare system, while fully respecting patients' rights and the rules of practicing medical professions;

¹ European Commission Communication "White Paper on Artificial Intelligence - A European Approach to Excellence and Trust" COM (2020) 65 final of 19 February 2020.

² Commission communication of 25 April 2018 "Artificial Intelligence for Europe", COM(2018) 237 final.

³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, COM(2018) 233 final.

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(3) we plan to undertake legislative, educational, promotional and self-regulatory initiatives in order to popularize the idea of artificial intelligence and make stakeholders aware of the potential of AI tools for the Polish health care system;

(4) we believe that the partnership, institutionalized and substantive dialogue of the participants of the health care system is key to the implementation of AI solutions in health care.

WHO WE ARE?

The AI in Health Coalition consists of various entities, including technology, pharmaceutical and healthcare companies offering local and global healthcare. We are interested in the development of AI potential in the Polish health care system. We use and conduct research and development works on technologies enabling the use of AI in the field of, among others: medical care, including telemedicine and advanced diagnostics, management in health care, clinical trials, distribution of medicinal products. We create products (medicinal products and medical devices) that use these technologies.

OUR VALUES

- **Quality** - AI solutions in healthcare should create a new quality of healthcare services, allowing for more effective achievement of the goals of the healthcare system, in particular increasing the effectiveness of patient care.
- **Availability** - AI solutions in healthcare should be widely available for patients. They should not be addressed only to a narrow audience, but should also take into account practical aspects, including issues such as digital exclusion and health literacy.
- **Safety** - AI solutions in health care should ensure the safety of their users and medical professionals, including the safety of therapy.
- **Trust** - AI solutions in health care should respect the central role of a medical professional in patient care and inspire their trust. They should also respect patients' rights, including the right to privacy.
- **Knowledge** - the development of AI solutions in health care will allow for further improvement of AI technology (knowledge about AI) and will enable the effective use of data generated by the health care system (knowledge thanks to AI).

OUR GOALS

Main Goals:

- the Polish healthcare system should widely and quickly use AI solutions that are effective, safe and efficient;

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- AI solutions should take into account the key role of the doctor and other medical staff - AI solutions should support medical staff and allow them to focus more attention on the patient;
- AI solutions should make it possible to improve the efficiency of the system, both in terms of financial (savings) and medical and organizational (more effective use of medical staff working hours);
- AI solutions should increase the effectiveness and quality of patient treatment and broaden access to healthcare services;
- the Polish health care system should develop at the same pace with the progress of science and technology, without system delays;
- at the system level, AI solutions should be effectively and efficiently implemented by stakeholders.

Operational goals:

- development of sectoral public policies that take into account the importance of AI in health care and their implementation, including, in particular, a dedicated sectoral policy for artificial intelligence in the healthcare sector, along with a measurable implementation plan;
- ensuring the availability and quality of medical data for the purpose of providing medical care and conducting scientific research (including research and development) by adopting a strategic law regulating these issues and corresponding to contemporary challenges and needs;
- developing a proposal of tools supporting the development of artificial intelligence, taking into account the specificity of the health care sector, including mechanisms for disseminating knowledge in institutions, creating measures of benefits from the use of AI solutions and financial instruments addressed to entrepreneurs;
- cooperation with the public party as part of an institutionalized discussion platform aimed at defining educational, technical, organizational and regulatory activities aimed at maximizing the benefits of implementing AI solutions in the health sector.

BARRIERS TO THE DEVELOPMENT OF AI IN HEALTH PROTECTION

In order to achieve the goals described above, the first step is to break down the basic barriers to development that exist today.

The main barrier is currently **the low quality and barriers to accessing medical data**. The legal system should ensure easy and efficient access to data, which will take place with the informed consent of the data subject or in a manner that does not infringe the patient's rights (e.g., access to anonymous data). The current regulations in this respect are inconsistent and unclear, and they do

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not ensure the quality of data, in particular data collected in medical registers. Numerous legal doubts are raised by the admissibility of further processing of medical data without the consent of the subject of personal data. These doubts are related to, inter alia, with the lack of a national legal framework in this regard. The idea of data donation is not being promoted.

Other barriers are:

- **Awareness** - currently, the level of knowledge about possible technological solutions in the field of AI is low. Optimal use of the potential of artificial intelligence in the medical and pharmaceutical sector will require awareness-raising and involvement of various stakeholders in the health system, including patients, medical workers, healthcare providers, scientists, universities, pharmaceutical and medical device companies, and the public party;
- **Financing** - the current mechanisms of financing from public funds for the development and use of AI algorithms in health care are insufficient. Public sector participation in the form of transfer of funds or limitation of certain burdens (e.g., taxes) in the formula prescribed by law would contribute to the development of AI tools for the health care system;
- **Law** - currently, there are no legal regulations regarding artificial intelligence. It is also desirable to create a legal framework for developing an AI development policy and tools to measure the benefits of implementing AI solutions.

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2nd Appendix - formula of the Declaration of will to join the AI in Health Coalition

_____ (date)

DECLARATION OF WILL TO JOIN THE AI IN HEALTH COALITION

Acting for and on behalf of _____ (hereinafter: "member of the Coalition") based in _____, hereby declares the will to join the AI in Health Coalition as a main / supporting member * (delete as appropriate). I therefore support the Manifesto of the AI in Health Coalition, and I also declare that I have read the Terms & Conditions of the AI in Health Coalition and fully accept its provisions. I declare that the contact person / persons representing / representing a member of the Coalition as part of the Coalition's work will be / will be:

_____, e-mail adress: _____

_____, e-mail adress: _____

_____, e-mail adress: _____

I also declare that:

- a) contact details of persons representing a member of the Coalition will be updated on an ongoing basis;
- b) contact persons familiarized themselves with the information obligation set out in Annex 3 to the Coalition Regulations.

[name and surname, institution]

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3rd Appendix – GDPR Clause

1. The administrator of your personal data is Ligia Kornowska, running a business under the name "MEDEXPERT LIGIA KORNOWSKA-NAJBUK" with its registered office in Warsaw, ul. Żelazna 59 apt. 1405, 00-848 Warsaw, entered into the Central Register and Information on Economic Activity of the Republic of Poland kept by the minister responsible for economy, NIP: 5272863628, REGON: 381172361 (hereinafter: data administrator).
2. You can contact us via e-mail: biuro@aiwzdrowiu.pl or phone number: +48 690 875 075.
3. Your personal data is processed by the Data Administrator in connection with the will to join the AI in Health Coalition, the leader of which is the Data Administrator.
4. Providing data is voluntary, but failure to do so will prevent participation in the AI in Health Coalition.
5. The scope of your personal data processed by the Administrator includes name and surname, e-mail address, name of the position or function held, professional experience relevant to the implementation of the goals of the AI in Health Coalition.
6. Your personal data will be processed for the purpose of performing the contract if you are a member of the AI in Health Coalition, which is the Regulations of the AI in Health Coalition - Article 6 (1) (b) of the GDPR.
7. If you are a representative of a member of the AI in Health Coalition, the legal basis for processing is the legitimate interest of the Data Administrator - Article 6 (1) (f) of the GDPR – the legitimate interest of enabling the Administrator to efficiently perform the contract for the operation of the AI in Health Coalition, and the data Administrator has received from the entity that is represented by you.
8. Your personal data may be transferred to suppliers of IT systems and IT services, entities providing the Administrator with services necessary to perform the contract for the operation of the AI in Health Coalition in accordance with the Regulations (e.g., external consultants, external accounting staff).
9. Your personal data will be processed for the period of operation within the AI in Health Coalition, this period may be extended by the time necessary to establish, investigate or defend against claims related to the contract.
10. You have the right to access your data and the right to request their rectification, removal or limitation of their processing, the right to object to the processing, and the right to transfer data.
11. You also have the right to lodge a complaint with the supervisory body dealing with the protection of personal data in the Member State of your habitual residence, place of work or place of the alleged infringement
12. Your data will not be transferred to a third country.

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