INFORMATION AND CONSENT FOR THE PROCESSING OF PERSONAL DATA

Dear Dr.,

Pursuant to Regulation (EU) 2016/679 and the subsequent national transposing laws (jointly, the "**GDPR**"), with this privacy information notice we wish to inform you about the processing of your personal data by OPIS S.r.l., with registered office in Desio (20832), in via Matteotti 10 ("**OPIS**"), collected and subsequently processed by OPIS, in its capacity as "Data Processor", mainly in the context of clinical trials in which the Company participates on behalf of its sponsors.

1. **CATEGORIES OF PERSONAL DATA PROCESSED**

OPIS shall collect, store, and process the following categories of personal data, including the data contained in the résumés requested from time to time:

- your personal identification data and contact details (name, family name, email address, telephone number, address);
- the accounts and data associated with the use by the physician of the electronic CRF or of any other platforms made available by OPIS with respect to the clinical trial in which the physician is invited to participate;
- information about the organisation/s you are employed with or provide services to, or were employed with or provided services to in the past;
- information about your professional skills, including your education and your specialisation/s, publications, participations in meetings, and areas of interest;
- information about your participation in any previous trials and/or initiatives supported by OPIS;
- financial information, including information about shareholdings and any other information regarding possible conflicts of interest, including family relationships and other relevant data;
- information about the treatments prescribed and the reports regarding pharmacovigilance; and
- information about the management of cases involving compassionate use and any clinical trials autonomously managed on behalf of clinical centres and healthcare organizations.

2. PURPOSES AND LEGAL GROUNDS FOR THE PROCESSING

2.1 Your personal data shall be processed by OPIS lawfully and confidentially, by electronic means and/or on paper, in compliance with law provisions, for the purposes specified herein below.

2.2 Under applicable law provisions and the contractual obligations undertaken by OPIS as a Clinical Research Organization ("**CRO**"), in its capacity as "Processor":

a) to create and manage an account in your name on websites or platforms of OPIS which you use to participate in clinical trials and to carry out any related activities or to participate in training sessions and online courses;

b) more in general, to allow you to participate, as principal investigator or collaborator, in clinical trials or in observational studies supported by OPIS, as well as in any related investigators' meetings;

c) to communicate with sponsors, ethics committees and domestic, EU and non-EU public authorities (such as AIFA, EMA, TrialGov, etc.);

d) in the context of any activities associated with compassionate use and pharmacovigilance, as well as any collaboration with clinical centres and healthcare organizations for autonomously managed, non-sponsored trials.

2.3 with reference to OPIS's legitimate interest and in its capacity as "Data Controller":

a) to create and keep, also after the end of the clinical trials, individual profiles for each physician in specific databases, which are aimed at identifying and indicating/suggesting to its clients (such as sponsors) the most suitable physician/s for a specific trial and at communicating to such clients the contact details of the identified physician/s, as well as for the purpose of assessing your level of satisfaction regarding the conduct of the trial;

b) to maintain and protect the IT systems, and to manage any loss and/or destruction of data and unauthorised access;

c) to examine and improve the quality of the services we provide to our sponsors, manage insurance risk, manage and internally monitor our activities, carry out statistical analyses, and, when necessary, exercise our right to initiate legal proceedings before a Court;

d) unless you object to the processing, to allow OPIS to contact you by email or by telephone to invite you to participate in new clinical trials, in meetings and in other initiatives directed at physicians, and to send you notices regarding OPIS's activities.

2.4 Communicating your personal data:

a) for the purposes referred to in paragraph 2.2., is necessary to allow you to access the services provided on OPIS's websites and platforms, as well as to allow you to take part in the clinical trials to which you have been invited to participate. Communicating your personal data is mandatory, and, in case of failure to do so, OPIS shall not be able to continue the trial;

b) for the purposes referred to in paragraph 2.3, is necessary in the context of OPIS's legitimate interest and of your legitimate expectation to be taken into account and contacted by the Company for subsequent clinical trials and other initiatives relating to your profession. With reference to the processing referred to in paragraph 2.3 d), **you have the right to object, at any time, to the processing of your personal data for the foregoing purposes.** In the event of an objection, OPIS shall not contact you and have you involved in any further initiatives, but shall only manage your contact details for the purposes associated with the trial to which you have been invited to participate.

3. DATA PROCESSOR

3.1 Your personal data shall be processed by duly trained employees/collaborators of OPIS, as well as by any persons that, on behalf of OPIS and in accordance with the instructions provided by the latter, have been appointed to carry out certain tasks or to conduct specific stages relating to the data processing, such as by way of example the allocation, management and maintenance of the electronic databases of OPIS, or other supporting, instrumental and ancillary activities, such as the transmission of information and/or documents. In this case, the processor shall select only third parties that, based on experience, skills and reliability, provide sufficient guarantees to meet the requirements set forth by the applicable law provisions governing data processing, including all security-related provisions.

3.2 OPIS has appointed a Data Processor Officer (DPO) who may be contacted at the following email address: dpo@opis.it

4. SECURITY MEASURES

OPIS has implemented specific security measures to ensure protection of the personal data, in compliance with the GDPR requirements, thereby minimizing any risks of unauthorized access or disclosure, improper use, alteration, unlawful or accidental destruction and loss. In this regard, OPIS has performed a risk assessment of its IT systems in line with the types of data processed, the circumstances and the purposes of the processing, as well as the state of the art.

5. RECIPIENTS OF PERSONAL DATA AND TRANSFER OF PERSONAL DATA TO COUNTRIES OUTSIDE THE EUROPEAN UNION

5.1 Your data may be communicated to the following categories of recipients: sponsors, business partners of OPIS, CRAs, ethics committees, domestic, EU and non-EU public authorities (such as AIFA, EMA, TrialGov, etc.), parent and subsidiary companies of OPIS, sub-contractors, freelance collaborators and other suppliers of OPIS, including service providers, and other public authorities, by way of implementation of the applicable law provisions, and in the context of any inspections conducted by the foregoing institutions and entities for the purpose of assessing compliance with the laws governing clinical trials.

5.2 Your personal data may be transferred abroad, including to countries outside of the European Union, for the aforementioned purposes relating to the management of the clinical trials, as well as for technical and information needs. In these cases, appropriate safeguards shall be provided for the protection of your personal data (including by means of *ad hoc* contractual commitments).

5.3 Furthermore, your personal data may be subject to dissemination in the cases required by law for the purpose of transparency in scientific research activities, as well as upon publication of the results of the study in which you participated. Unless otherwise expressly required by law or on the grounds of public health interests, all results shall be published and disseminated on an aggregate and anonymous basis.

6. RIGHTS OF THE DATA SUBJECT

6.1 OPIS hereby informs you that you have the right to request confirmation as to whether or not personal data concerning you is being processed and, in any case, the right to obtain access to your personal data and to request the rectification, completion or updating thereof.

6.2 You also have the right to request the erasure, anonymization or blocking of any personal data unlawfully processed or of data whose retention is no longer necessary for the purposes hereunder, as well as to object to the processing of your personal data as indicated in paragraph 2.3 d) herein above, or to request restriction of the processing.

6.3 In addition to the rights described above, you also have a right to data portability, if technically feasible based on the collection methods, on contractual grounds or if you have provided specific consent therefor.

6.4 You may exercise your rights at any time, by contacting OPIS at the DPO's email address indicated above, or by sending an email to privacy@opis.it.

6.5 You may also file a complaint with the Personal Data Protection Authority (*Garante per la protezione dei dati personali)* if you believe your personal data have been unlawfully processed.

7. DATA STORAGE AND RETENTION

7.1 Your personal data will be retained for the entire duration of the clinical trial and also after the end of the trial for the time necessary pursuant to the law and as requested by the sponsor in its capacity as Data Controller.

7.2 Your personal data and the profiles contained in the company's databases for the purposes indicated in paragraph 2.3 d) shall be stored and retained, unless you have submitted a specific and legitimate request for erasure, for a period of 5 years as of the last contact with you.

7.3 The log files and data relating to your account on the website and platforms of OPIS shall be retained for 2 years as of your last access, unless you have submitted a request for erasure beforehand.