**Participant information letter**

**The European Essential Drug List for medical education, a Modified Delphi Study**

Dear,

You are asked to participate in a medical education scientific study. Participation is voluntary. Your digital informed consent is required prior to participating.

You are asked to participate in this study because you are selected by a colleague who is a (principal) teacher in clinical pharmacology and therapeutics in the European Network of Teachers in Pharmacotherapy (NOTIP).

This study is conducted by Amsterdam University Medical Centers, VU University Amsterdam on behalf of the Education working group of the European Association of Clinical Pharmacology and Therapeutics (EACPT). The executive researcher is Erik Donker, PhD-student at Amsterdam UMC. This study has been approved by the Ethical Review Board Committee of the Netherlands Association for Medical Education (NVMO) and the Medical Ethics Committee of Amsterdam UMC (VUmc) has decided that this study does not fall within Medical Research Involving Human Subjects Act (WMO).

Prior to participation, you are informed about this research. Please read this letter carefully and feel free to ask additional questions to the research.

**1. Purpose of the study**

The purpose of the study is to construct a list of available drugs which are standard practice to prescribe and which a European junior doctor must be able to prescribe safely and effectively without supervision. This will improve and harmonise the design of education and training in clinical pharmacology and pharmacotherapy (CP&T) in all medical curricula in Europe.

**2. Expectations**

This is a Delphi consensus study among experts in the field of education in CP&T. The study consists of two parts, conducted through the online survey programme Castor EDC.

Part 1 (starting date: 23rd of August 2021):

In part 1 we do not expect any input from your side. In this part of the study the local NOTIP coordinator will evaluate all separate drugs on availability in your country.

Part 2 (starting date: 4th of October 2021):

Part 2 will consists of two rounds (each 3 weeks). In both rounds we will send a list of drugs and ask you to evaluate two statements per drug:

1. "In my country, it is standard practice to prescribe this drug to patients."
2. "A junior doctor must be able to prescribe this drug safely and effectively without supervision."

There is also room to note down suggestions of missing drugs. Both rounds will take approximately 40 minutes to complete. It is possible to complete a portion of the survey and return later to finish the remaining part.

This research requires that we collect additional information from you. It concerns personal data as described in point 5. See there for further explanation.

**3. Possible disadvantages, risks and benefits**

You do not gain any (direct) benefit from participating in this study. Your participation can contribute to more safe prescribing of (junior) physicians in Europe and it will support and harmonize the educational programs in clinical pharmacology and pharmacotherapy in Europe. Risks and disadvantages associated with participation are slim: we ask you for a

time-investment of around 50 minutes in total.

**4. Participation**

It is up you to decide whether or not participate in this survey. Participation is entirely voluntary. Your decision and answers will not be shared with the local NOTIP coordinator. If you decide to participate in the study, you can stop participating at any time during the study and without giving a reason. Your data collected in the survey will be deleted and not used in this study. Only data that is already send to the other participants for round 2, and the actual publication cannot be retracted. If you have already signed the electronic consent form, you can announce your withdrawal via email to e.donker@amsterdamumc.nl.

**5. Data processing and storing**

For this study it is necessary to collect personal data. This concerns your: email address, ~~age, gender~~, university affiliation, profession, number of years of clinical experience, number of years of teaching. The personal data will not be visible to other respondents.

All data is collected in the confidential and secure system Castor EDC (GDPR and ISO 27001 & 9001 certified). After collection, data will be stored in a separate directory on the secure server of Amsterdam UMC, VUmc that only the research team has access to. This data will be coded, meaning that every participant will have a code that is used instead of the name and other personal identifiable information. Only the two researchers (Erik Donker and David Brinkman) knows which code is linked to which participant. At publication, all data will be fully anonymized and untraceable back to you. We will never publicize individual responses together with a name, university or country. Therefore, at publication, all data will be fully anonymized and untraceable back to you.

If you participate in this study, you consent to data being stored for 10 years after ending the study for further analysis within context of this study. After 10 years, the data will be destroyed. When requested, we will destroy your data within 10 years after ending the study, but published or submitted data will not be retracted. Prior to using data outside the context of the current study, we will always contact you for additional consent. The executive researcher will always contact you for interim relevant information. Upon request via e-mail you will receive an electronic copy of your own data.

For more information about your rights on data processing, you can contact Erik Donker via e.donker@amsterdamumc.nl. Erik Donker is responsible for lawful data processing. If you are dissatisfied about how we handle your privacy, you may file a complaint to our privacy officer via privacy@vumc.nl. You can also contact the Dutch Data Protection Authority (DPA) via https://autoriteitpersoonsgegevens.nl/en/contact-dutch-dpa/contact-us.

**6. Compensation**

There will be no compensation for participating in this study, except that all participating experts will be listed as contributor to the resulting journal article.

If you have any remaining questions, please contact Erik Donker via [e.donker@amsterdamumc.nl](mailto:e.donker@amsterdamumc.nl) or +31 20 444 8090.

Thank you for your interest in this study.

Yours sincerely,

Erik Donker, MD

David Brinkman, MD, PhD

Milan Richir, MD, PhD

Jelle Tichelaar, MD, PhD

**Research Centre:**

Section Pharmacotherapy

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**Informed consent form**

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* I have read the information letter for participants. I have had the opportunity to ask additional questions. My questions have been sufficiently answered. I have had enough time to decide whether to participate or not.
* I know that participation is entirely voluntary. I am aware of my right to withdraw or end my participation from the study at any time. I do not need to justify that decision.
* I know that certain people have access to my data. These people are listed in this information letter. I am entitled to inquire and look into how my data are stored.
* I consent to my data being used in the way and for the purpose stated in the information sheet. If for any reason my data would be used for research with another objective, I will be informed and again be asked to consent.
* I consent to my data being stored for another 10 years after ending this study to permit further analysis within the context of this study.
* I know that when requested, the executive researcher will destroy my data within 10 years after ending the study, but shared, published or submitted data will not be retracted.



*This is a digital informed consent form, built into CastorEDC. If participants select Yes, they will be able to continue the rest of the survey. If participants select no, they will be prompted the message: “Without consent you cannot participate.” And they will not be able to continue to the rest of the survey. The date and timestamp is automatically logged the moment the survey is completed. (As the survey cannot be viewed without consent, this means that consent is always given prior to completion).*