### **Pre-deployment Questionnaire**

#### Phase 1 - Context and purpose

#### A. General information:

- a. Describe the context and the specific purpose of the AI system.
- b. When (dd/mm/yyyy) will the AI system begin operation?
- c. Specify the end date if known, or estimate the duration in months/years.
- d. Usage Frequency: How many times per day/week/month will the AI system be used? Provide an exact count.
- e. What are the expected outputs of the AI system and how will they be used in decision-making processes?
- f. Is the AI system classified as High-risk under article 6 of the AI Act and why?
- g. Does the AI system have a GenAI component?
- h. Does the GenAI component present systemic risks as defined by the AI Act, and if so, what are the specific factors contributing to this assessment?

### B. Categories of natural persons and groups

- a. Who are the affected persons?
- b. Are there any categories of natural persons that can be considered as more vulnerable groups? What are their specific risks?
- c. Who will directly interact with the AI system?

### Phase 2.1 - Deployment process section

- a. What type of algorithm(s) or model will be used? Please provide detailed examples and context for each risk level.
  - i. a non-self-learning algorithm in which humans specify the rules the computer must comply to (risk level 1 to 3)
  - ii. a System that is entirely or partially based on a self-learning algorithm, where the machine itself is finding patterns in the data (choose a risk level from 4 to 10)

- b. Among different alternatives suitable to achieve similar goals and performances, do you plan to use a simpler and more explainable algorithm?
  - i. Yes (choose a risk level between 1 and 5)
  - ii. No. Please explain your choice (choose a risk level between 6 and 10)

### Deployment process section risk level:

### Phase 2.1 - Input data and Fairness section

- a. Are all input data (from internal and external sources), including third-party training data and data added by the Deployer, governed by data governance and data quality processes?
  - i. Yes, all, in compliance with GDPR, AIA and IP requirements (risk level 1)
  - ii. Only partially (e.g., in case a model has been pre-trained by an external provider and there are no warranties about data used). Please specify (choose a risk level between 2 and 10)
  - iii. No1

RISK LEVEL: COMMENT:

- b. If the AI system includes a GenAI component and it uses personal data to produce the output, could this lead to the generation of unexpected and/or undesired content? Do not count this question for the Risk Indicator calculation in case the System has no GenAI components or if it does not use personal data to produce the output.
  - i. Yes (risk level 10)
  - ii. No (risk level 1)

RISK LEVEL: COMMENT:

c. Have you or your Provider analyzed the input data to assess possible biases that could lead to a negative impact on fundamental rights? Please specify your choice and provide detailed examples.

<sup>&</sup>lt;sup>1</sup> If the Team selected this answer, the Questionnaire shall be suspended.

- i. Yes, please specify (e.g. in Fairness Assessment or data exploration, documentation provided by the Provider) (choose a risk level between 1 and 10).
- ii. No<sup>2</sup>

- d. Have you or your Provider collected all the relevant and available data needed to assess if the algorithm may discriminate against or disadvantage specific population subgroups (e.g., nationality, gender, age, etc.)? Please specify your choice and provide detailed examples.
  - i. Yes, please specify (e.g. in Fairness Assessment, data exploration, or in order to do this assessment; choose a risk level between 1 and 10)
  - ii. No<sup>3</sup>

# RISK LEVEL: COMMENT:

- e. Do you or your provider plan to monitor the trend over time of fairness metrics and/or AI System performance referring to specific population subgroups? Please specify your choice and provide detailed examples.
  - i. Yes (choose a risk level between 1 and 5)
  - ii. No (choose a risk level between 6 and 10)

### RISK LEVEL: COMMENT:

### **Input data and Fairness section risk level:**

### Phase 2.1 - Transparency section

- a. Are the components of the AI System and their outputs explainable, interpretable and/or verifiable?
  - i. Yes, all the components are designed to be explainable, interpretable and/or verifiable. Describe what techniques are employed (Choose a risk level from 1 to 3)

<sup>&</sup>lt;sup>2</sup> If the Team selected this answer, the Questionnaire shall be suspended.

<sup>&</sup>lt;sup>3</sup> If the Team selected this answer, the Questionnaire shall be suspended.

- ii. Not all the components of the AI System are explainable, interpretable and/or verifiable. Describe what techniques are employed (Choose a risk level from 4 to 10)
- iii. No<sup>4</sup>

- c. Have you identified the subjects (Provider, Deployer, and Affected persons) for which the output of the AI System shall be made sufficiently understandable?
  - i. Yes (risk level 1)
  - ii. No<sup>5</sup>

#### **RISK LEVEL:**

#### **COMMENT:**

- d. Are the AI System outputs designed as sufficiently understandable for the Deployer?
  - i. Yes (choose a risk between 1 and 10)
  - ii. No6

#### **RISK LEVEL:**

#### **COMMENT:**

- e. If applicable, are the AI System outputs designed as sufficiently understandable for the staff and other persons dealing with the operation and use of AI system on behalf of the Deployer? If not applicable, do not consider this question within the Risk indicator calculation.
  - i. Yes (choose a risk between 1 and 10)
  - ii. No<sup>7</sup>

#### **RISK LEVEL:**

#### **COMMENT:**

- f. If applicable, are the AI System outputs designed as sufficiently understandable for the affected person? If not applicable, do not consider this question within the Risk indicator calculation.
  - i. Yes (choose a risk level between 1 and 10)
  - ii. No<sup>8</sup>

<sup>&</sup>lt;sup>4</sup> If the Team selected this answer, the Questionnaire shall be suspended

<sup>&</sup>lt;sup>5</sup> If the Team selected this answer, the Questionnaire shall be suspended

 $<sup>^{6}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

 $<sup>^{7}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

<sup>&</sup>lt;sup>8</sup> If the Team selected this answer, the Questionnaire shall be suspended

### **Transparency section risk level:**

#### Phase 2.2 - Performance section

- a. Have you planned to test the AI system performance and proper functioning?
  - i. Yes (choose a risk level between 1 and 10)
  - ii. No<sup>9</sup>

If yes, specify what is the metric chosen for that purpose and what is the frequency of the testing. On the basis of which evaluation criteria is a metric value considered acceptable (ex. acceptable thresholds)?

RISK LEVEL: COMMENT:

Performance section risk level:

### Phase 2.3 - Human Oversight section

- a. What is the degree of automated decision-making in the AI system?
  - i. The decision is taken by a human being and the AI System provides only an additional layer of information (Choose a risk level between 1 and 2)
  - ii. The decision is made by the application of AI System are only executed after human review or approval (Choose a risk level between 3 and 4)
  - iii. The decision relies on the AI System, but it is possible for a human to override the outcomes (Choose a risk level between 5 and 10)
  - iv. The decision-making process is completely reliant on the AI System, without possibility for overrides<sup>10</sup>

- b. Can the operation of the AI system be interrupted through a 'stop' button or similar procedure?
  - i. Yes, intervention possible (choose a risk level between 1 and 10)

 $<sup>^{9}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

<sup>&</sup>lt;sup>10</sup> If the Team selected this answer, the Questionnaire shall be suspended

ii. No, intervention is not possible. Provide details<sup>11</sup>

# RISK LEVEL: COMMENT:

- c. Is it ensured that the staff and other persons dealing with the operation and use of AI systems on behalf of the Deployer and the Provider have the means to interact with the AI system and use it in an informed and conscious manner?
  - i. Yes, those subjects have received a specific training and they can consult technical guidelines or support. Please specify. (choose a risk level from 1 to 4)
  - ii. Yes, those subjects have received a specific training but they can not consult technical guidelines or support. Please specify (choose a risk level from 5 to 10)
  - iii. No, those subjects have not been trained for the specific purpose<sup>12</sup>

RISK LEVEL: COMMENT:

- d. Are there support mechanisms for the subjects mentioned above designed to address issues or concerns with AI system operation?
  - i. Yes (risk level 1)
  - ii. No (risk level 10)

RISK LEVEL: COMMENT:

### **Human Oversight section risk level:**

### Phase 2.4 - AI system Monitoring and Maintenance

- a. If unfair behavior emerges, will it be possible to intervene to correct it?
  - i. Yes, it will be possible to intervene (risk level 1)
  - ii. No, it has been not possible to correct the unfair behavior<sup>13</sup>

<sup>&</sup>lt;sup>11</sup> If the Team selected this answer, the Questionnaire shall be suspended

 $<sup>^{12}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

<sup>&</sup>lt;sup>13</sup> If the Team selected this answer, the Questionnaire shall be suspended

- b. Do you plan to adopt monitoring techniques and related countermeasures in order to intercept anomalous behavior or performance deterioration?
  - i. Yes (risk level between 1 and 10)
  - ii. No<sup>14</sup>

- c. How do you plan to update the AI system (retrain, tune, knowledge source update, etc)?
  - i. Update not needed given the AI system's technical features (rule-based system without variations over time) (risk level 1)
  - ii. Not applicable, as in the case of GenAI Systems, either the AI system has been integrated by external providers (i.e. "proprietary models") or its update is economically too burdensome and operationally unnecessary (risk level between 2 and 9).
  - iii. Manual or automatic update planned (e.g., using new data, re-estimation of the hyperparameters of the model, vector store update in RAG applications.) (choose a risk level between 1 and 9)
  - iv. No update planned (risk level 10)

RISK LEVEL: COMMENT:

- d. Have you planned procedures for emergency/urgent updates?
  - i. Yes, please describe (choose a risk level between 1 and 5)
  - ii. No (choose a risk level between 6 and 10)

- e. Have you planned any processes in order to ensure the ongoing and continued availability of data, coherently to the business needs?
  - i. Not needed since not foreseen by business requirements (risk level 1)

<sup>&</sup>lt;sup>14</sup> If the Team selected this answer, the Questionnaire shall be suspended

- ii. Yes (choose a risk level between 1 and 5)
- iii. No (choose a risk level between 6 and 10)

- f. Do you plan to oversee the stability of input data/features used by the AI system?
  - i. Yes, overseeing the stability of input data and features has been planned with one or more of these options (choose a risk level between 1 and 5):
    - 1. General and specific quality controls of input data
    - 2. Trend analysis of input data
    - 3. Trend analysis of Model features
    - 4. Specific Data Drift synthetic measures
    - 5. Evaluation of suitability/toxicity of prompts
  - ii. Input data quality controls already in place are deemed as effective safeguards and no other actions are planned (choose a risk level between 6 and 9)
  - iii. No action planned (risk level 10)

RISK LEVEL: COMMENT:

AI System Monitoring and Maintenance section risk level:

QRI:

### Post-deployment Questionnaire

Please note that in a real scenario the post-deployment Questionnaire is completed only after the AI system has been deployed, incorporating any new information that arises postdeployment. This post-deployment Questionnaire serves a different purpose than the one used during the design phase, so it must be filled out from scratch rather than relying on responses previously provided during the design stage.

### Phase 1 - Context and purpose

#### B. General information:

- i. Describe the context and the specific purpose of the AI system.
- j. When (dd/mm/yyyy) will the AI system begin operation?
- k. Specify the end date if known, or estimate the duration in months/years.
- 1. Usage Frequency: How many times per day/week/month will the AI system be used? Provide an exact count.
- m. Resource Requirements: Quantify required resources (e.g., 100 CPU hours/week, 2 full-time operators).
- n. What are the expected outputs of the AI system and how will they be used in decision-making processes?
- o. Is the AI system classified as High-risk under article 6 of the AI Act and why?
- p. Does the AI system have a GenAI component?
- q. Does the GenAI component present systemic risks as defined by the AI Act, and if so, what are the specific factors contributing to this assessment?

### B. Categories of natural persons and groups

- d. Who are the affected persons?
- e. Are there any categories of natural persons that can be considered as more vulnerable groups? What are their specific risks?
- f. Who will directly interact with the AI system?

### Phase 2.1 - Deployment process section

c. What type of algorithm(s) or model have been used? Please provide detailed examples and context for each risk level.

- i. a non-self-learning algorithm in which humans specify the rules the computer must comply to (risk level 1 to 3)
- ii. a System that is entirely or partially based on a self-learning algorithm, where the machine itself is finding patterns in the data (choose a risk level from 4 to 10)

- d. Among different alternatives suitable to achieve similar goals and performances, have you chosen a simpler and more explainable algorithm?
  - iii. Yes (choose a risk level between 1 and 5)
  - iv. No. Please explain your choice (choose a risk level between 6 and 10)

# RISK LEVEL: COMMENT:

### **Deployment process section risk level:**

### Phase 2.1 - Input data and Fairness section

- f. Are all input data (from internal and external sources), including third-party training data and data added by the Deployer, governed by data governance and data quality processes?
  - iv. Yes, all, in compliance with GDPR, AIA and IP requirements (risk level 1)
  - v. Only partially (e.g., in case a model has been pre-trained by an external provider and there are no warranties about data used). Please specify (choose a risk level between 2 and 10)
  - vi. No<sup>15</sup>

- g. If the AI system includes a GenAI component and it uses personal data to produce the output, could this lead to the generation of unexpected and/or undesired content? Do not count this question for the Risk Indicator calculation in case the System has no GenAI components or if it does not use personal data to produce the output.
  - iii. Yes (risk level 10)
  - iv. No (risk level 1)

 $<sup>^{15}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended.

- h. Have you or your Provider analyzed the input data to assess possible biases that could lead to a negative impact on fundamental rights? Please specify your choice and provide detailed examples.
  - iii. Yes, please specify (e.g. in Fairness Assessment or data exploration, documentation provided by the Provider) (choose a risk level between 1 and 10).
  - iv. No16

# RISK LEVEL: COMMENT:

- i. Have you or your Provider collected all the relevant and available data needed to assess if the algorithm may discriminate against or disadvantage specific population subgroups (e.g., nationality, gender, age, etc.)? Please specify your choice and provide detailed examples.
  - iii. Yes, please specify (e.g. in Fairness Assessment, data exploration, or in order to do this assessment; choose a risk level between 1 and 10)
  - iv. No<sup>17</sup>

# RISK LEVEL: COMMENT:

- j. Did you or your provider monitor the trend over time of fairness metrics and/or AI System performance referring to specific population subgroups? Please specify your choice and provide detailed examples.
  - iii. Yes (choose a risk level between 1 and 5)
  - iv. No (choose a risk level between 6 and 10)

RISK LEVEL: COMMENT:

### Input data and Fairness section risk level:

 $<sup>^{16}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended.

<sup>&</sup>lt;sup>17</sup> If the Team selected this answer, the Questionnaire shall be suspended.

### Phase 2.1 - Ownership and Control

- a. Does the AI System use software libraries, and/or modules that have been developed by third parties (e.g., pretrained models, outsourced code, ...)? Please specify your choice and provide detailed examples.
  - i. No, AI System has been developed internally and/or using documented and accessible open-source libraries (e.g., pandas, scikit-learn) (risk level 1)
  - ii. Yes (risk level 10)

RISK LEVEL: COMMENT:

### Ownership and control section risk level:

### Phase 2.2 - Transparency section

- b. Are the components of the AI System and their outputs explainable, interpretable and/or verifiable?
  - iii. Yes, all the components are designed to be explainable, interpretable and/or verifiable. Describe what techniques are employed (Choose a risk level from 1 to 3)
  - iv. Not all the components of the AI System are explainable, interpretable and/or verifiable. Describe what techniques are employed (Choose a risk level from 4 to 10)
  - v. No<sup>18</sup>

RISK LEVEL: COMMENT:

- g. Have you identified the subjects (Provider, Deployer, and Affected persons) for which the output of the AI System shall be made sufficiently understandable?
  - i. Yes (risk level 1)
  - ii. No<sup>19</sup>

RISK LEVEL: COMMENT:

h. Are the AI System outputs sufficiently understandable for the Deployer?

 $<sup>^{18}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

<sup>&</sup>lt;sup>19</sup> If the Team selected this answer, the Questionnaire shall be suspended

- i. Yes (choose a risk between 1 and 10)
- ii. No<sup>20</sup>

- i. If applicable, are the AI System outputs sufficiently understandable for the staff and other persons dealing with the operation and use of AI system on behalf of the Deployer? If not applicable, do not consider this question within the Risk indicator calculation.
  - i. Yes (choose a risk between 1 and 10)
  - ii. No<sup>21</sup>

RISK LEVEL: COMMENT:

- j. If applicable, are the AI System outputs sufficiently understandable for the affected person? If not applicable, do not consider this question within the Risk indicator calculation.
  - i. Yes (choose a risk level between 1 and 10)
  - ii. No<sup>22</sup>

RISK LEVEL: COMMENT:

### **Transparency section risk level:**

### Phase 2.3 - Performance section

- b. Have you tested the AI system performance and proper functioning?
  - iii. Yes (choose a risk level between 1 and 10)
  - iv. No<sup>23</sup>

If yes, specify what is the metric chosen for that purpose and what is the frequency of the testing. On the basis of which evaluation criteria is a metric value considered acceptable (ex. acceptable thresholds)?

#### **RISK LEVEL:**

<sup>&</sup>lt;sup>20</sup> If the Team selected this answer, the Questionnaire shall be suspended

 $<sup>^{21}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

 $<sup>^{22}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

<sup>&</sup>lt;sup>23</sup> If the Team selected this answer, the Questionnaire shall be suspended

#### **COMMENT:**

#### **Performance section risk level:**

### Phase 2.4 - Human Oversight section

- e. What is the degree of automated decision-making in the AI system?
  - i. The decision is taken by a human being and the AI System provides only an additional layer of information (Choose a risk level between 1 and 2)
  - ii. The decision is made by the application of AI System are only executed after human review or approval (Choose a risk level between 3 and 4)
  - iii. The decision relies on the AI System, but it is possible for a human to override the outcomes (Choose a risk level between 5 and 10)
  - iv. The decision-making process is completely reliant on the AI System, without possibility for overrides<sup>24</sup>

### RISK LEVEL:

#### **COMMENT:**

- f. Can the operation of the AI system be interrupted through a 'stop' button or similar procedure?
  - i. Yes, intervention is possible (choose a risk level between 1 and 10)
  - ii. No, intervention is not possible. Provide details<sup>25</sup>

### RISK LEVEL:

#### **COMMENT:**

- g. Is it ensured that the staff and other persons dealing with the operation and use of AI systems on behalf of the Deployer and the Provider have the means to interact with the AI system and use it in an informed and conscious manner?
  - Yes, those subjects have received a specific training and they can consult technical guidelines or support. Please specify. (choose a risk level from 1 to 4)
  - ii. Yes, those subjects have received a specific training but they cannot consult technical guidelines or support. Please specify (choose a risk level from 5 to 10)

<sup>&</sup>lt;sup>24</sup> If the Team selected this answer, the Questionnaire shall be suspended

 $<sup>^{25}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

iii. No, those subjects have not been trained for the specific purpose<sup>26</sup>

# RISK LEVEL: COMMENT:

- h. Are there support mechanisms for the subjects mentioned above designed to address issues or concerns with AI system operation?
  - i. Yes (risk level 1)
  - ii. No (risk level 10)

RISK LEVEL: COMMENT:

### **Human Oversight section risk level:**

### Phase 2.5 - AI system Monitoring and Maintenance

- g. If unfair behavior emerged, was it possible to intervene to correct it?
  - i. No, no unfair behavior emerged (risk level 1)
  - ii. Yes. Please specify what kind of interventions have been implemented (choose a risk level between 1 and 10)
  - iii. No, it was impossible to correct the unfair behavior<sup>27</sup>

RISK LEVEL: COMMENT:

- h. Did you adopt monitoring techniques and related countermeasures in order to intercept anomalous behavior or performance deterioration?
  - i. Yes (risk level between 1 and 10)
  - ii. No<sup>28</sup>

RISK LEVEL: 4 COMMENT:

i. How do you plan to update the AI System (retrained, tuned, knowledge source update, etc)?

 $<sup>^{26}</sup>$  If the Team selected this answer, the Questionnaire shall be suspended

 $<sup>^{</sup>m 27}$  If the Team selected this answer, the Questionnaire shall be suspended

<sup>&</sup>lt;sup>28</sup> If the Team selected this answer, the Questionnaire shall be suspended

- i. Update not needed given the AI system's technical features (rule-based system without variations over time) (risk level 1)
- ii. Not applicable, as in the case of GenAI Systems, either the AI system has been integrated by external providers (i.e. "proprietary models") or its update is economically too burdensome and operationally unnecessary (risk level between 2 and 9).
- iii. Manual or automatic update planned (e.g., using new data, re-estimation of the hyperparameters of the model, vector store update in RAG applications.) (choose a risk level between 1 and 9)
- iv. No update planned (risk level 10)

- j. Are there in place procedures for emergency/urgent updates?
  - i. Yes, please describe (choose a risk level between 1 and 5)
  - ii. No (choose a risk level between 6 and 10)

# RISK LEVEL: COMMENT:

- k. Are there any processes in order to ensure the ongoing and continued availability of data, coherently to the business needs?
  - i. Not needed since not foreseen by business requirements (risk level 1)
  - ii. Yes (choose a risk level between 1 and 5)
  - iii. No (choose a risk level between 6 and 10)

- 1. Do you oversee the stability of input data/features used by the AI system?
  - i. Yes, the stability of input data and features is overseen with one or more of these options (choose a risk level between 1 and 5):
    - 6. General and specific quality controls of input data
    - 7. Trend analysis of input data
    - 8. Trend analysis of Model features
    - 9. Specific Data Drift synthetic measures
    - 10. Evaluation of suitability/toxicity of prompts

- ii. Input data quality controls already in place are deemed as effective safeguards and no other actions are planned (choose a risk level between 6 and 9)
- iii. No action have been done (risk level 10)

AI System Monitoring and Maintenance section risk level:

QRI: