HEU EFS
HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

**H**armonised approach to **E**arly **F**easibility **S**tudies for Medical Devices in the **E**uropean **U**nion **(HEU-EFS)**

# WP5 Program monitoring system

# DELIVERABLE 5.1

## Assessing the Performance of Early Feasibility Studies in the EU – Annex I – Online Form #1

COCIR Advancing Healthcare · efpia · EuropaBio The European Association for Bioindustries · MedTech Europe from diagnosis to cure · Vaccines Europe

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**Disclaimer:**

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# HEU-EFS_WP5/WP7_Form #1_Checklist

Start of Block: Default Question Block

**HEU-EFS Form #1 - Self-Evaluation Checklist** This online form is designed to collect preliminary data from sponsors participating in the EFS pilot. Your responses will remain confidential, and no individual sponsors or medical device technologies will be identifiable. Should you have any questions or comments please contact Giuditta Callea (giuditta.callea@unibocconi.it).

Please generate a self-selected, 8 digit code that will serve as unique identifier of the EFS pilot. Your code may include letters, numbers, and special characters:

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**Pilot overview information**

Q1 Does the sponsor of the EFS identify itself as a SME? Note: The European Commission defines Small and medium-sized enterprises (SMEs) as enterprises with fewer than 250 employees and either an annual turnover below €50 million or a balance sheet total under €43 million.

- O Yes (1)
- O No (2)

Q2 Company name (optional)

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Q3 Representative name (optional)

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Q4 Representative contacts (optional)

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Q5 When are you planning to submit the EFS application?

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Q6 Please select the option that describes the pilot EFS based on the number of countries and clinical sites involved:

- O Single-country, single-centre (1)
- O Single-country, multi-centre (2)
- O Multiple-country, multi-centre (3)

Q7 Which of the following EU/EEA NCAs do you plan to submit the EFS application to? Please check all that apply.

- [ ] Austria (Austrian Agency for Health and Food Safety (AGES) (1)
- [ ] Czech Republic (State Institute for Drug Control) (2)
- [ ] Denmark (Danish Health and Medicines Authority) (3)
- [ ] France (Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)) (4)
- [ ] Germany (Federal Institute for Drugs and Medical Devices (BfArM)) (5)
- [ ] Ireland (Health Products Regulatory Authority) (6)
- [ ] Italy (Ministero della Salute) (7)
- [ ] Netherlands (Health and Youth Care Inspectorate) (8)
- [ ] Poland (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) (9)
- [ ] Spain (Spanish Agency for Medicines and Medical Devices) (10)

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Q8 If there were a coordinated assessment option under the EFS pilot, which NCA would you prioritize as the lead NCA?

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Q9 Please list the  ethics committees (EC) to be involved in the EFS pilot if known.

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Q10 Please list the clinical sites to be involved in the EFS pilot if known.

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Q11 Which of the following non-EU/EEA NCAs have you, or plan to, submit the EFS application to? Please check all that apply. If none, please select "None of the above."

- [ ] United States (FDA) (1)
- [ ] UK (MHRA) (2)
- [ ] Switzerland (Swissmedic) (3)
- [ ] New Zeland (MedSafe) (4)
- [ ] Georgia (RAMA) (5)
- [ ] Other (6) _____
- [ ] None of the above (7)

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**Technology characteristics**

Q12 What is the therapeutic area of the device?

- O Circulatory system (cardiovascular / lymphatic) (1)
- O Endocrinology and diabetes (2)
- O Gastroenterology and hepatology (3)
- O General and plastic surgery, dentistry (4)
- O Nephrology and urology (5)
- O Neurology (6)
- O Obstetrics and gynecology (including reproductive health) (7)
- O Ophthalmology (8)
- O Orthopedics, traumatology, rehabilitation (9)
- O Respiratory, anesthesiology, intensive care (10)
- O Other (11) _____

Q13 What is the highest risk classification of the device?

- O Class I (1)
- O Class IIA (2)
- O Class IIB (3)
- O Class III (4)

Q14 In case the technology is not Class III or Class IIb device (including DHTs) as per eligibility criteria (see deliverable D3.1), please provide a justification.

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Q15 Is the technology a breakthrough device and/or addressing an unmet need (i.e. no equivalent device exists)?

- O Yes (1)
- O No (2)

Q16 Is the technology already CE Marked or previously approved for clinical investigations such that the EFS pilot will be an expansion of the existing intended use in new patient population or application?

- O Yes (1)
- O No (2)

Q17 Is the purpose of the EFS pilot study to better understand the device interaction between the technology and physiology/anatomy during development?

- O Yes (1)
- O No (2)

Q18 Is the purpose of the EFS Pilot study to evaluate a technology enhancement made to an existing design?

- O Yes (1)
- O No (2)

Q19 Please describe why you consider this study as an EFS.

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Q20 Enter the number of subjects to be enrolled within EU.

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Q21 In case the estimated enrolment exceeds 15 patients as per eligibility criteria (see deliverable D3.1), please justify.

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Q22 What are the characteristics of the target patient population?

- O Male/Female (1) _____
- O Age range (2) _____
- O Other (4) _____

Q23 Does the study include phased or iterative enrolment?

- O Yes, please describe (1) _____
- O No (2)

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**Patient engagement**

Q24 Did you involve patients and/or patient organisations before, during, or after the EFS as advisors? This does not refer to patients who are study subjects/participants. *Examples of patient involvement include but are not limited to patient provision of advise on clinical endpoints, inclusion/exclusion criteria, informed consent documentation, communication strategies for adverse events, inclusion of patients/patient in the advisory board, follow-up with study participants.*

- O Yes (1)
- O No (2)

*Display this question:*
*If Did you involve patients and/or patient organisations before, during, or after the EFS as advisor... = Yes*

How did you involve patients and/or patient organisations as advisors? Please briefly describe the patient engagement activities, the objective of the activities, and at what stage of the EFS they took place.

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Q25 In line with section 3 of Annex XV of MDR have the vulnerable patient groups relevant to the health condition been identified, specifically subjects such as children, pregnant women, immuno-compromised or, elderly subjects, if they are included, please justify.

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**Level of pre-clinical evidence**

Q26 Is the EFS planned to be conducted in accordance with ISO 14155:2020?

- O Yes (1)
- O No (2)

Q27 Is the technology developed utilizing the principles of ISO 14971?

- O Yes (1)
- O No (2)

Q28 Is the technology under investigation compliant to GSPR for pre-clinical testing (unless duly justified)?

- O Yes (1)
- O As far as possible (2)
- O No (3)
- O No, the relevant data is planned to be collected during the EFS. (4)

Q29 Was generation of pre-clinical evidence possible?

- O Yes (1)
- O No (2)

*Display this question:*

*If Was generation of pre-clinical evidence possible? = Yes*

Q30 To the best of your knowledge has the sponsor exhausted all bench, in silico, or animal options?

- O Yes (1)
- O No (2)

Q31 If available, has data from similar devices or previous versions been consulted/leveraged?

- O Yes (1)
- O No (2)

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**Clinical expertise and clinical sites**

Q32 Are the clinical sites expected to comply with ICH-GCP standards?

- O Yes (1)
- O No (2)

Q33 Are the clinical sites expected to comply with ISO 14155:2020?

- O Yes (1)
- O No (2)

Q34 Does the personnel to be involved in EFS have an extensive understanding on how to report serious adverse events in line with requirements of the MDR and national law?

- O Yes (1)
- O No, please describe which personnel (2) _____

Q35 Does the clinical site have the capacity and equipment to offer adequate emergency care and support systems during and, where needed, after the EFS?

- O Yes (1)
- O No (2)

Q36 Does the clinical site staff have experience in the therapeutic field of the investigational devices?

- O Yes (1)
- O No (2)

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Q37 Does the clinical site staff have research experience with similar devices?

- O Yes (1)
- O No (2)

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Q38 Does the clinical site staff have experience in early phase clinical investigations?

- O Yes (1)
- O No (2)

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Q39 Does the site have direct access to the protocol defined patient population within the targeted recruitment period?

- O Yes (1)
- O No (2)

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Q40 Is there a developed training program for clinical personnel on the new technology to be investigated in the EFS?

- O Yes (1)
- O No (2)

Q41 Are proctors (independent physician with experience with the device) involved in the clinical staff training activities and case support?

- O Yes (1)
- O No (2)

Q42 Are clinical specialists (sponsor employee experienced with the function of the device) involved in the clinical staff training activities and case support?

- O Yes (1)
- O No (2)

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**End of Block: Default Question Block**

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