SC1-BHC-08-2020: New interventions for Non-Communicable Diseases

Specific Challenge: Non-communicable diseases represent a significant burden on individuals and healthcare systems, accounting for 86 % of all deaths in Europe. Innovative and effective healthcare interventions are required to find a cure or provide best quality of care when prevention strategies have failed. While considerable knowledge has been generated by biomedical research, potentially promising healthcare interventions often fail clinical validations and as a consequence do not reach patients.

Scope:

Proposals should conduct early stage[50] clinical trial(s) to validate novel or refined healthcare interventions[51] for patients suffering from non-communicable diseases (Rare diseases and regenerative medicine are not within the scope of this topic). Clinical trial(s) should be supported by proof-of-concept[52] of clinical safety and efficacy[53] and may be investigator-initiated. Both preclinical research and the draft clinical trial protocol should be completed at the time of submission of the proposal. Applicants should present a sound feasibility assessment, including an appropriate patient selection and realistic recruitment plans, justified by publications or preliminary results. Proposals should demonstrate potential clinical benefit, including consideration of patient-reported outcomes when relevant. Sex and gender differences should be considered; age and other stratification criteria[54] should be considered when relevant. Where appropriate, patients and carers should be involved and their views reflected in research activities. Proposals should demonstrate evidence of preliminary consultations with ethics and regulatory authorities at the time of submission.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- Candidate healthcare interventions that would generate meaningful advances in clinical practice and care for patients with non-communicable diseases for late stage clinical trials.
- Potential to improve patient-centred outcomes and to impact on the disease burden of individual patients and health care systems following validation in late stage clinical trials.

Type of Action: Research and Innovation action

50 For pharmacological interventions: phase 1 and phase 2 clinical trials

51 Applicants may address any mono- or combinatorial pharmacological and/or non-pharmacological intervention.

52 Comparative effectiveness studies are not within the scope of this topic.

53 Clinical Trial Regulation EU No. 536/2014: https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

54 Such as, clinical and molecular features of the patient and/or the disease, socio-economic status, etc.