EU4H-2021-JA-12: *Direct grants to Member States' authorities:* ***safety assessment cooperation and facilitated conduct of clinical trials***

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Safety cooperation in clinical trials under the CTR (EU)536/2014

- Implementing Regulation: cooperation in the assessment of suspected unexpected serious adverse events, ('SUSARs', Art 42) and annual safety reports ('ASR', Art 43)
- Work-share based cooperation, risk-proportionate assessments of world-wide, cross-trial safety information at active substance level
- IT support with integrated data from the Clinical Trials Information System, EudraVigilance Database and EU Medicinal Product Dictionary
- Strengthened oversight and increased scrutiny to reinforce clinical trials in generating high quality safety data and to improve the safety of current and future medicines on the EU market.
- COM adoption process has been initiated, target date for the application: 31 January, 2022 (same with CTR)

- BUT: there is a need for additional expertise and capacities at Member States to implement this new system

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EU4Health – sub-action for coordinated safety assessment in clinical trials

~ 5 M EUR in the 2021 work program for 3 years

- Direct grant for MSs (4.5 EUR in JA):
  - secretariat to support the coordination of different safety assessment activities
  - **salary for safety assessors** (including a mentoring/twinning program to train new safety assessors by senior safety assessors)
  - data depository (?)
  - https://ec.europa.eu/health/sites/default/files/funding/docs/wp2021_annex_en.pdf (page 78)

- Objective: improve the quality of safety data from clinical trials by reinforcing MS oversight
- Outcome: increased capacity and expertise for safety assessments, increased number of safety assessments, reduced redundancies
- Second wave: submission of nominations: 20/09-29/10
- Preliminary interest n=29: AT, BE, BG, CZ, DE, DK, EL, EE, ES, FI, FR, HR, HU, IE, IS, IT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK maybe later CY

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- Each JA needs a coordinator MS, discussions about the JA coordinator and work-package leaders has started
- Possibility for expedited assessment of the proposal and retroactive start of the grant

- Additional budget (0.5M EUR procurement to reimburse expenses) for an **expert exchange program**

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Thank you

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