EUROPEAN HEMATOLOGY ASSOCIATION

ACT EU Multistakeholder platform kick-off workshop

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An invigorated clinical trials environment needs to have Reduced Bureaucracy

- **Safety reporting**

  - We need to harmonize and simplify submission of adverse events by agreeing on a single harmonized investigator-friendly platform

  - Making use of the protocol to reduce excessive reporting, as per the Clinical Trials Regulation (CTR)

    "The investigator shall record and document adverse events or laboratory abnormalities identified in the protocol as critical to the safety evaluation and report them to the sponsor in accordance with the reporting requirements and within the periods specified in the protocol."

    "The investigator shall record and document all adverse events, unless the protocol provides differently. The investigator shall report to the sponsor all serious adverse events occurring to subjects treated by him or her in the clinical trial, unless the protocol provides differently"

- **Informed Consent**

  - We need to make sure the patients understand the information provided to them and what they are giving consent to

- **Regulatory Guidelines**

  - Making sure that the regulations that are developed and in place are aligned between the different areas and that they are clear, concise, consistent and proportionate to avoid overinterpretation and increasing administrative requirements.

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Thank you!