Comments for EC Public Consultation on recommendations for Risk proportionate approaches in clinical trials

Name of Organisation: Gilead Sciences International Ltd.
Category of Organisation: Company/Business

Line no.	Comments
192-199	The document suggests that a comprehensive assessment of potential risks and all mitigation measures put in place be included in the study protocol. Is it the new expectation that risk minimization measures should now include descriptions of Investigator/monitor training and other equally generic study measures that really form part of GCP and therefore can be considered expected? None of these measures are study-specific, so it could be argued that stating that the study is being conducted under GCP exonerates from the need to outline all processes in the protocol.
257-259	Given recent FDA guidance, even on post authorisation studies, the expectation for collection of AE/SAE has not been reduced. This would make it difficult to gain any benefit for a global study as we would have to go with the most conservative regulatory expectations.
262-264	With reference to the assessment and mitigation plan that is produced in conjunction with the protocol development, is there to be a template and is this for every protocol? It seems there is an approach to simplify the study but more requirements are added to the study set up.
269-272	*"...reporting requirements for adverse events that may be adapted in the protocol, in line with the scope type of a clinical trial and the level of knowledge on the safety profile of the IMP tested and the disease profile of the trial subjects. This means in practice that the protocol may select only certain (and not all) adverse events to be recorded and reported to the sponsor."* Same comments as for lines 257-259 above. In addition, the example cited in line 298 with oncology trials and cytotoxic affects – how will a study be able to identify any impact of the IMP under investigation on such therapy if events are not collected?
319-323	There is a requirement to capture the description of the DSMB processes in the protocol. As above, it seems that more and more

	requirements are being set for the content of the protocol, potentially leading to a document that is very large and less likely to be read in detail by key stakeholders.