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EU Consultation Document: Risk proportionate approaches in clinical trials [June 2016]			
Page Number	**Text Line**	**Reference** *(if applicable)*	**Comments**
3	75-81		ACRP commends the expert group for developing this comprehensive statement to address risk proportionate approaches across all types of clinical trials, including those using novel IMPs as well as marketed products in commercially sponsored research and in academic and public health studies.
3-13	55, 62, 122, 129, 136, 140, 378, 463		Use of the term "normal clinical practice" as ***the*** key measure against which relative or additional risks are to be assessed is likely to be subject to considerable variation for a given clinical trial, unless the trial is conducted at a single clinical trial site. At some points in this document, the phrase is combined with "in the Member State concerned," perhaps to address what practice differences may be observed between Member States. But even within a single Member State, normal clinical practices can vary by more locally identified conduct standards or, possibly, by certain local restrictions. For many multi-national clinical trials, clinical practice uniformity in terms of the quality and availability of clinical care at trial sites is not often observed. Even within the EU region, practice variability may be seen among recommendations made by various medical professional organizations, governmental and private insurers, as well as at the community hospital policy level. Some community hospitals may even consider their practice standards at variance from the professional services rendered by their nearby colleagues in private practice settings. The clinical trial sponsor, IEC and regulatory authority may consider all these variations as having "normal clinical practice" status, but the risk-based decisions for study conduct and monitoring should account for this range of normal clinical practices to arrive either at some common denominator, or by adjusting the assessment by clinical trial site. So while Section 4 addresses study-wide issues very well, ACRP recommends that "normal clinical practice" variability be addressed in the Consultation Document.