The 2010 FDA IND Safety Reporting Regulation requires sponsors to report serious and unexpected adverse events associated with INDs. However, a 2016 FDA analysis showed stable to increased numbers of reports from 2011-2015. The 2010 FDA IND Safety Reporting Regulation requires sponsors to report serious and unexpected adverse events associated with INDs. The first project developed recommendations that offered an approach to harmonization, legal liability, over-riding investigator determinations, and thresholds for aggregate reporting. The second project aimed to identify 1) sponsor challenges to full implementation and motivation to change practice in order to fully associate with safety reporting. The first project developed recommendations that offered an approach to harmonization, legal liability, over-riding investigator determinations, and thresholds for aggregate reporting. 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