Regulatory Updates Worksheet Handout

Category	Challenge	Strategy (call to action)
Regulatory Authorities European Medicines Agency (EMA) United States of America – Food and Drug Administration (FDA) United Kingdom – Medicines and Healthcare products Regulatory Agency (MHRA) World Health Organization	• Keeping up with the changes/requirements • Guidelines may be vague, open to interpretation • Electronic or hard copy submissions • Updated Form FDA 1572- sites notified by sponsor communication, online websites, South African Clinical Research Association (SACRA) (local CRO)	• Identification of the regulatory authorities • Identify responsible party at the site (Clinical Research Site (CRS) Coordinator, Site Regulatory Manager, Quality Assurance (QA) Staff) to have contact with the regulatory bodies • Basic requirements of the identified regulatory authorities • Join networking groups such as SACRA and attend the quarterly meetings/workshops to build relationships and keep up-to-date with guidelines, etc. • Trackers used at site for different activities such as pregnancies, Serious Adverse Events (SAEs), Informed consent forms
Institutional Review Board/Independent Ethics Committee (IRB/IEC)	• Keeping up with submission requirement timelines • Keeping up with continuing review submission timelines • Ethics committees that do not send formal notification to the sites of approval.	• Basic requirements of the IRB/IEC • Standard Operating Procedures (SOP)s relating to the functioning of the IRB/IEC • Dates of meetings for the IRB/IEC • Continuing Review Tracker • Register to be added to the mailing lists for notifications on updates • Trackers used at site for different activities such as pregnancies, SAEs, Informed consent forms • Ensure that the site has documented the different timelines for reporting safety events to regulatory authorities

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Country Regulatory Bodies	• Require Ethics Committee Approval first – ensure that you are aware of the requirements and timelines • Requirements that impact site activations • Regional and country-specific regulatory requirements for safety reporting may be more restrictive than ICH • Country specific regulation changes – becoming aware of the changes and implementation of them • Only finding out the changes when you make an error • Different methods of notification of country regulation changes: online South African Health Products Regulatory Authority (SAHPRA), SACRA, and other websites, SAHPRA communication/memo (mailing list), SAHPRA workshops (annual), SACRA communication/ meetings, local ethics boards will communicate with regulatory department, annual meetings which site representatives attend • Guidelines may be vague, open to interpretation	• Join networking groups such as SACRA and attend the quarterly meetings/workshops • Trackers used at site for different activities such as pregnancies, SAEs, Informed consent Forms (ICFs) • Ensure that your site is aware and tracking regional and country-specific regulatory requirements and ensure compliance for safety reporting • Department of Health (DoH) or Department: Agriculture, Forestry and Fisheries (DAFF) - Memo through the South African Health Products Regulatory Authority (SAHPRA) contact list

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Division of AIDS (DAIDS)	• Notifications when policies change • Comprehension and training on new policies • Variation in site staff notification of DAIDS policy changes: updates during conferences + emails from networks/DAIDS/CTU Coordinator to CRS Coordinator/Leader but methods of disseminating information to other site staff may vary • Monitors may have different interpretations of the policies	• DAIDS expectations of the sites • DAIDS related trainings at site • DAIDS related websites and accesses required for sites • Register to be added to the mailing lists for notifications on updates • Login into the DAIDS-specific websites and peruse the uploaded documents for updates • Ensure that your site is aware and tracking DAIDS Safety Reporting process • CRS Coordinators, CTU PIs and other relevant key site staff to be notified by email - this is being done already • DAIDS to have more than one contact person per site to receive important Memos
Site Specific SOPs/Policies	• Process for creating, approving, implementing • Training staff on policies • Annual review to ensure they are up to date and accurately reflect processes.	• Identification of relevant SOPs for sites • Review period for site specific SOPs • Training for site specific SOPs • Request to participate as a member of the review committee to keep up-to-date and contribute to process • Establish relationships with the key staff involved so that you are notified when changes occur • Ensure that CRS Leader determines how information is to be distributed to site staff

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Other	• Staffing/responsibility at sites, some have departments/Clinical Research Organizations (CROs) that are responsible • Protocol Training - Need to know what is unique about a protocol (protocol training) in order to submit properly within timelines to IRB and avoid deviations if possible • Documents like protocol events, non-compliances, and deviations need to be reviewed by quality AND regulatory to ensure that it meets all requirements and that it is actually sent to the authorities – there are times when I am not copied on the emails when these are reviewed, and they end up being sent late to the authorities because of this lack in communication • Awareness by all site staff that if certain requirements are not adhered to i.e. notifying of SAEs on time, progress reports, ICF violations, etc., the authorities can visit the site unannounced and perform an inspection. This can sometimes lead to the site being suspended or closed completely.	• Significant/relevant communication should be documented via email, in writing and/or in meeting/training minutes. Email communication is best between sites and sponsor, sites and other sites, sites and DAIDS. • Significant communication to be maintained/filed in an organized fashion and accessible to all relevant site staff • Policy document/SOP for site regarding process of disseminating information to all relevant parties (regulation changes, etc.) • Bi-weekly meetings (or a portion of a staff meeting) set aside for regulatory updates/submission deadlines/regulatory training topics • Protocol-specific training for all study staff (on initial version as well as amendments) • SOP on how protocol training I completed at the site • SOP/update to QMS/CQMP to include QC measures for review of reportable events, prior to submission