

## Country Approval Spec

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Company: Thermo Fisher Scientific

Location: Uganda

Category: arts-design-entertainment-sports-and-media

- Prepares, review and coordinates local regulatory submissions (MoH, EC, additional special national local applications if applicable, gene therapy approvals, viral safety dossiers, import license) in alignment with global submission strategy.
- Provides local regulatory strategy advice (MoH &/or EC) to internal clients.
- Develops and implements local submission strategy. Provides technical expertise and coordination oversight for projects in collaboration with relevant internal departments.
- Serves as primary contact for investigators and with the local regulatory authorities (in collaboration with the local regulatory manager for complex issues) to ensure submissions are managed in a timely manner.
- Ensures guidelines and processes are followed for effective internal PPD team communications as well as communications with investigators, and with the country regulatory authorities to ensure submissions are managed in a timely manner.
- Acts as a key-contact at country level for all submission-related activities.
- Participates as required in Submission Team Meetings, Review Meetings and Project Team meetings.
- Coordinates with internal functional departments to ensure various site start-up activities are aligned with submissions activities and mutually agreed upon timelines; ensures alignment of submission process for sites and study are aligned to the critical path for site activation.
- Achieves PPD's target cycle times for site activations.
- Prepares the regulatory compliance review packages, as applicable.
- Liaise within SIA locally to ensure local submission activity is planned and delivered in

accordance with global project submission strategy.

- Develops country specific Patient Information Sheet/Informed Consent form documents.
- May assist with grant budgets(s) and payment schedules negotiations with sites.
- Assists in identifying and recognizing local out of scope activities in a contract in a timely manner and advise relevant functions.
- Supports the coordination of feasibility activities, as required, in accordance with agreed timelines.
- Ensures that trial status information relating to SIA activities are accurately maintained in the database and is current at all times.
- Oversees country study files and ensures that they meet PPD WPD's or client SOP's.
- Maintains knowledge of and understand PPD SOPs, Client SOPs/directives, and current regulatory guidelines as applicable to services provided.
- Directs/mentos other SIA individuals assigned to support projects of responsibility, as appropriate
- Proactively identifies issues or anomalies in the regulatory process of a study, resolves or escalates as appropriate.

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