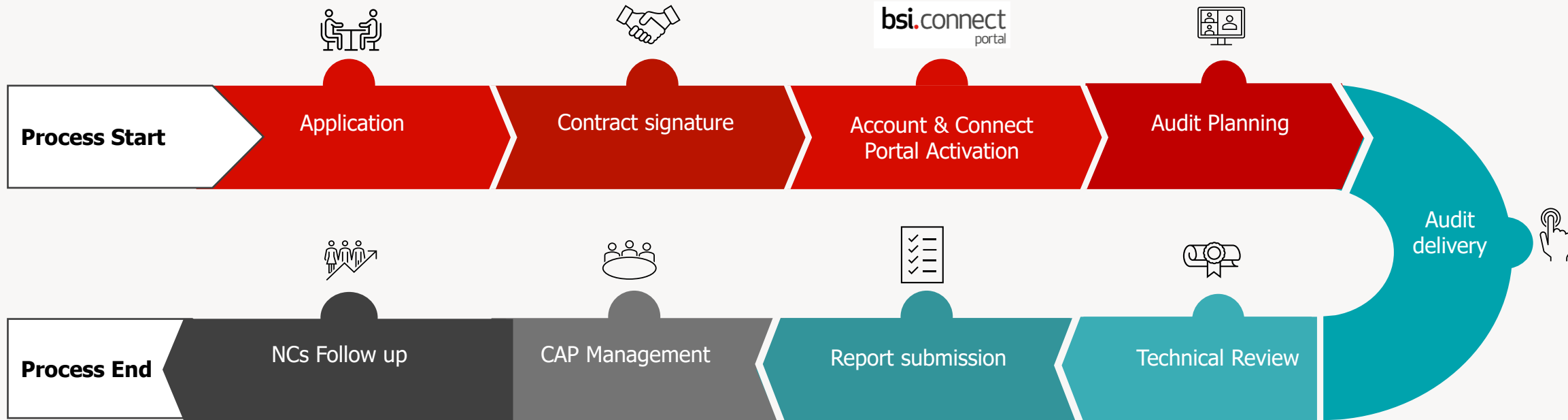


Process map

Phase 1: Application and Onboarding Phase 2: Audit Phase 3: CAPA



Phase	Description
Application	The supplier initiates contact with 3 rd Party audit firm and ask to be audited.
Contract signature	The supplier signs a Contract with the audit firm before any exchange of information takes place.
BSI Connect Portal activation	3 rd Party audit firm activates the Audit platform. The supplier receives an automatic email providing with the URL for the Audit platform.
Audit Planning	3 rd Party audit firm provides the supplier with an audit agenda and a Pre-Audit Document checklist which comprises documents/information which should be available during the audit. If the audit is to be partly or fully remote, assess technology requirements, data sharing platforms and any limitations such as ability to perform virtual site tour etc.
Audit delivery	The overall audit execution process consists of the following steps: 1) Opening Meeting 2) Site Tour 3) Interviews 4) Document Review 5) Pre-closing Meeting 6) Closing Meeting
Technical Review	A technical review and quality check of the report draft by the 3 rd party audit firm will take place to ensure that the audit has been documented according to requirements described in the current version of the QAP standard. The quality check covers as a minimum a completeness check and classification of findings.
Report submission	The final Audit Report will be shared through the Audit platform.
CAP Management	After receiving the Audit Report, the supplier should submit the Corrective Action Plan through the Audit platform, within agreed deadlines.
NCs Follow up	In case the verification methods were defined as "follow up visit" or the corrective action evidence cannot be effectively verified by a desk top review, a follow up audit needs to be scheduled. This follow-up audit is not a full audit, but a shorter visit to verify if adequate corrective actions have been taken in response to an audit finding.