ii4sm

healthcare ▸ context ▸ value

International Institute for the Safety of Medicines

QIX

Quality Information Exchange

An illustration of how quality information can be integrated across organisations

October 13, 2010

What is the Quality Information Exchange (QIX)

The Quality Information Exchange (QIX) is a suite of tools and services to enable research organisations to collaborate effectively with their partners and each other

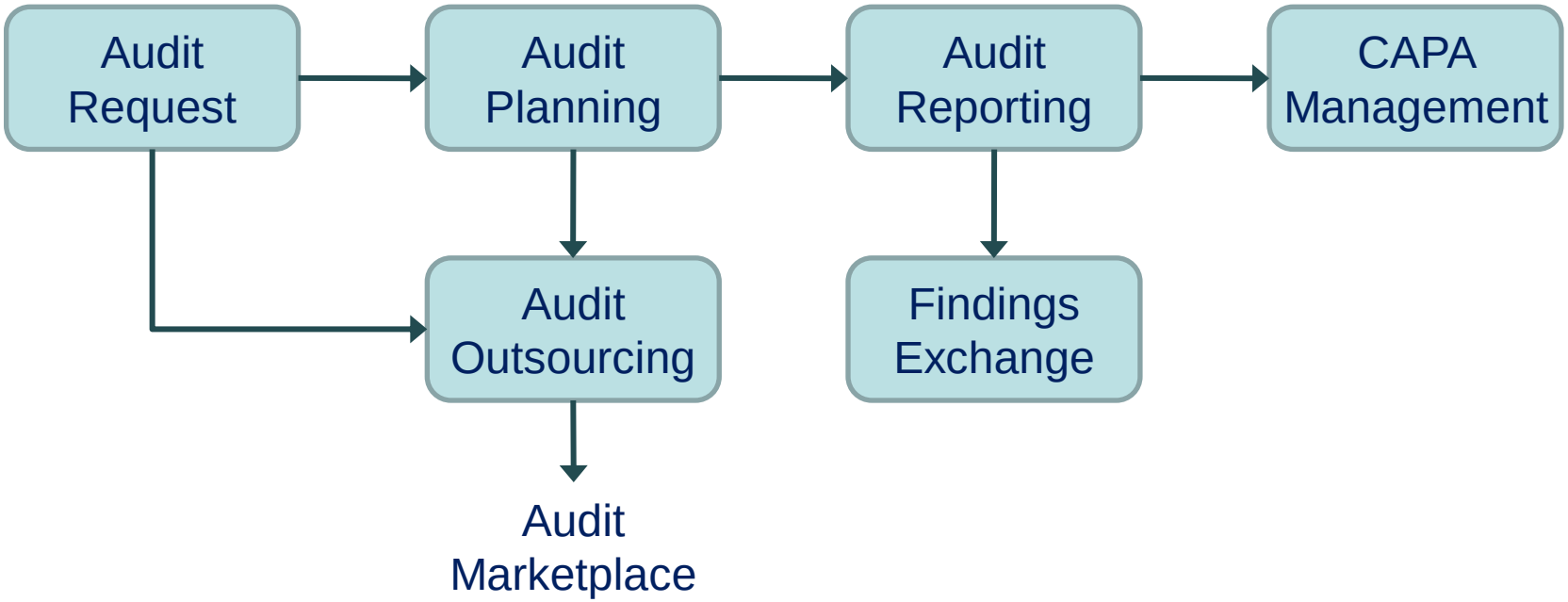
- Quality Information Exchange is the ability to jointly exchange information about
  - (Audit) scheduling and planning
  - (Auditor) performance, auditee feedback and service level of service providers
  - Findings, including positive ‚non-findings' to create a quality baseline

- Exchange of GCP QA information enables
  - Better scheduling, planning and targeting of audits
  - Risk baseline specification, benchmarking and objective comparison of performance

- This presentation is an example and illustration of
  - How operational data for risk management in GCP QA can be captured and shared
  - The example is focussed on transactional and performance data not medical content
  - The principles illustrated here can be applied to a broad set of trial planning activities

QIX Software Module Overview

QIX software modules complement each other and offer operational flexibility to suit individual organisational needs and extensibility to include new data sources



The software is available as a hosted service so that users can access it worldwide, eliminate maintenance and enable the coordination of activities and mapping of data

Creating Audit requests

Collecting and managing audit requests already creates valuable risk information and helps to focus QA resources more effectively

Quality Information Exchange

ii4sm healthcare context value

QIX Home > Audit Request > Create Audit Request

Log Out

- Home
- Audit Request
- Audit Planning
- Audit Marketplace
- Findings Exchange

Name: ORGA.PM
Org: COMPANYA
Login At: 14:28

Create Audit Request

Audit ID	
Audit Type	--Audit Type--
Audit Category	--Audit Category--
Priority	--Priority--
Auditee	
Location	Please Select Auditee First
Start Period	Sep - 2010
End Period	Sep - 2010
Duration (Days)	
Scope	
Objective	

Quality Information Exchange

ii4sm healthcare context value

QIX Home > Audit Request > Review Audit Request

Log Out

- Home
- Audit Request
- Audit Planning
- Audit Marketplace
- Findings Exchange

Name: ORGA.PM
Org: COMPANYA
Login At: 14:28

Pending Audit Requests

Auditee	Category	Start Period	End Period	Duration	Region	Audit ID
Pharma Research Unit	PreInspection	Okt, 2010	Okt, 2010	2 Days	North America	A0004
Pharma Research Unit	PreInspection	Okt, 2010	Okt, 2010	3 Days	North America	A0005
Pharma Research Unit	PreInspection	Okt, 2010	Okt, 2010	5 Days	North America	A0006
Pharma Research Unit	ForCause	Sep, 2010	Sep, 2010	5 Days	North America	A0007
Global CRO	Routine	Sep, 2010	Sep, 2010	3 Days	North America	A0101
Global CRO	Routine	Okt, 2010	Okt, 2010	5 Days	North America	A999

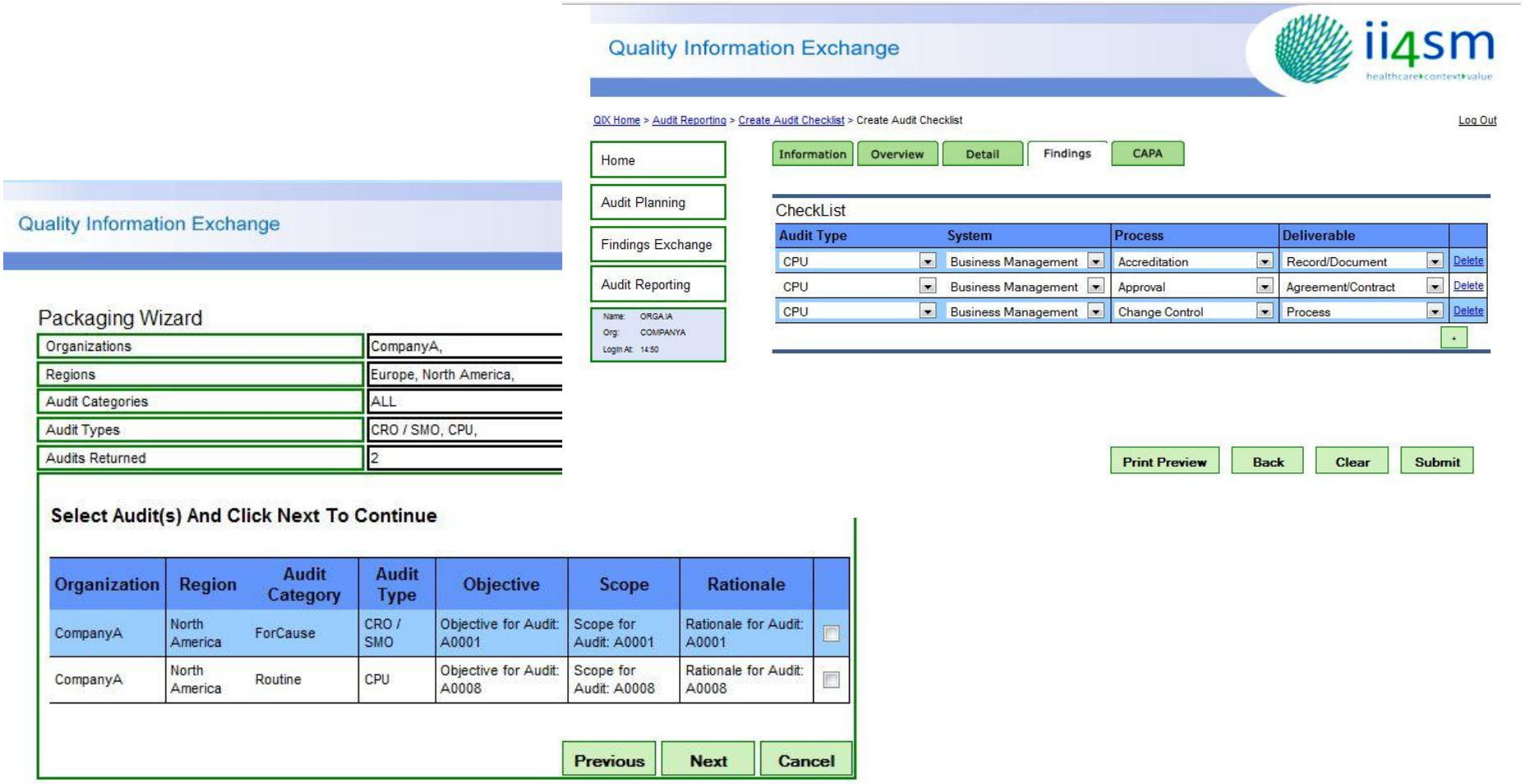
Audit Request Summary

Filter By: Category (All) | Regions (All) | Status (Any)

Auditee	Category	Start Period	End Period	Duration	Region	Status	Audit ID
Pharma Research Unit	ForCause	Sep, 2010	Sep, 2010	5 Days	North America	Approved	A0001
Ultra sound facility	Routine	Sep, 2010	Sep, 2010	3 Days	North America	Approved	A0002
Ultra sound facility	Routine	Sep, 2010	Sep, 2010	5 Days	North America	Approved	A0003
Pharma Research Unit	Inspection	Okt, 2010	Okt, 2010	4 Days	North America	Approved	A0008
Pharma Research Unit	ForCause	Sep, 2010	Sep, 2010	3 Days	North America	Approved	T001
	Routine	Okt, 2010	Okt, 2010	0 Days		Approved	asr22
	ForCause	Nov, 2010	Nov, 2010	0 Days		Approved	asr26
Pharma Research Unit	ForCause	Sep, 2010	Sep, 2010	2 Days	North America	Approved	a444
CompanyA	Inspection	Sep, 2010	Sep, 2010	3 Days	Europe	Approved	A555

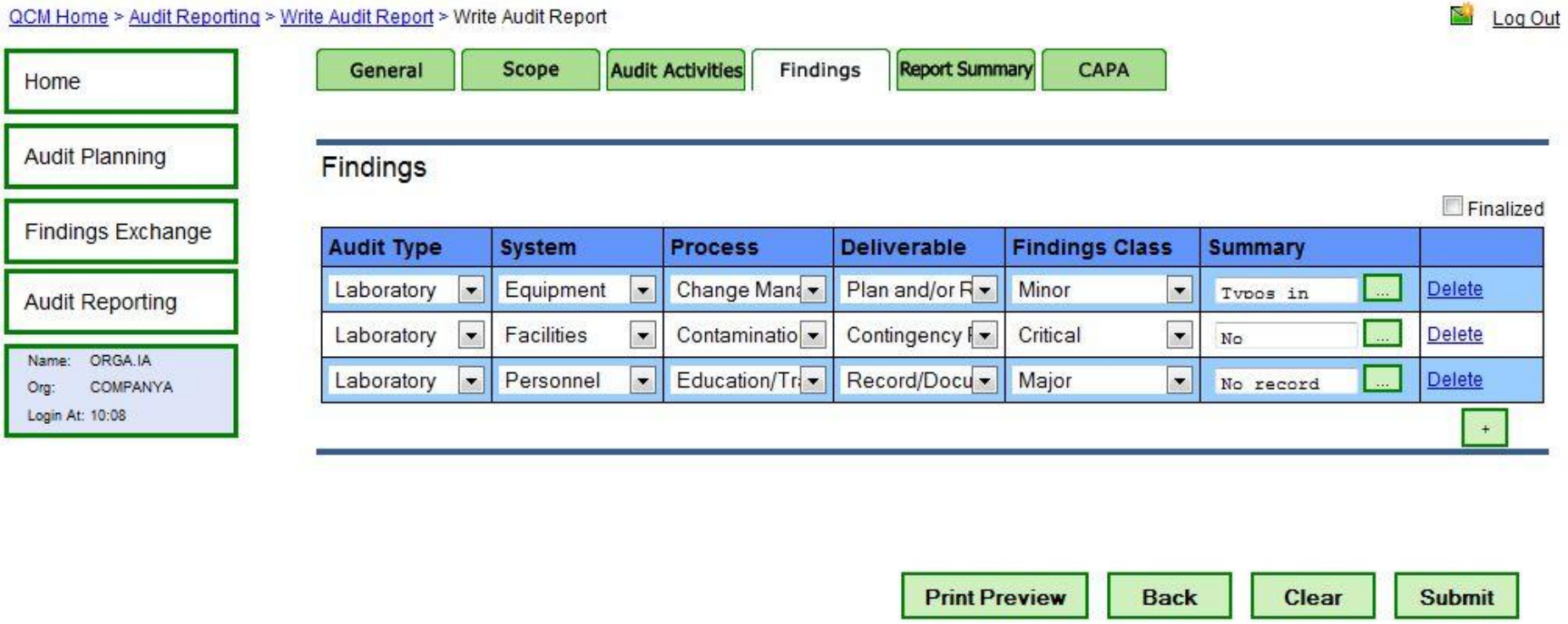
Audit Planning

Packaging audits and creating checklists enables audit planners to specify the focus and details that need to be audited in a structured and standardised way



Structuring Findings (and 'non-findings')

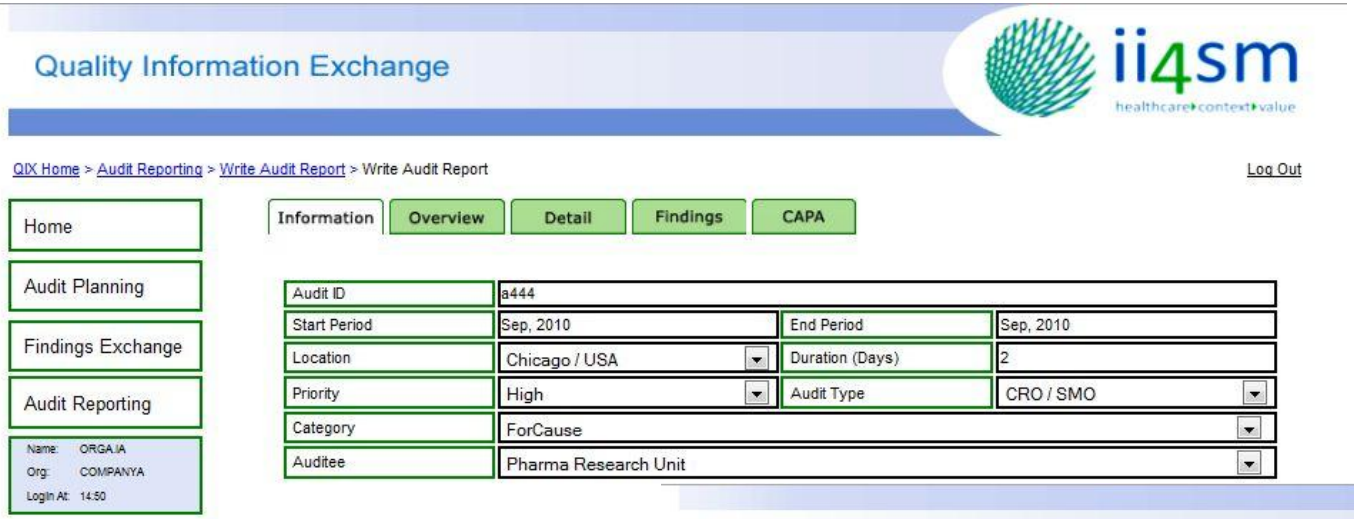
The audit report findings 'grid' enables like-for-like comparisons between findings and for organisations to map findings to a common meaning

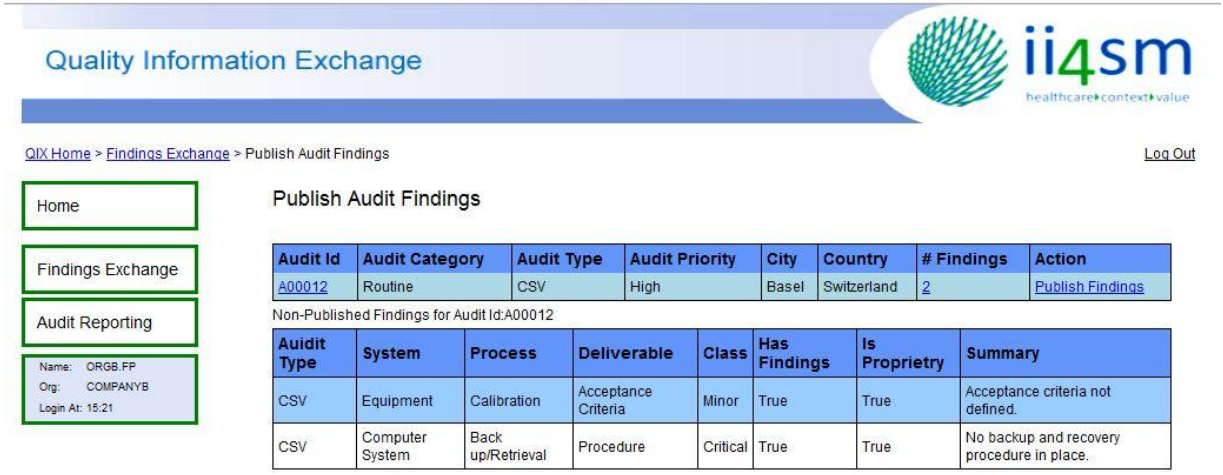


This also enables organisations to map their terms to a common environment and report on both negative 'findings' & positive 'non-findings' to create quality baselines

Audit Report Writing and Findings Publication

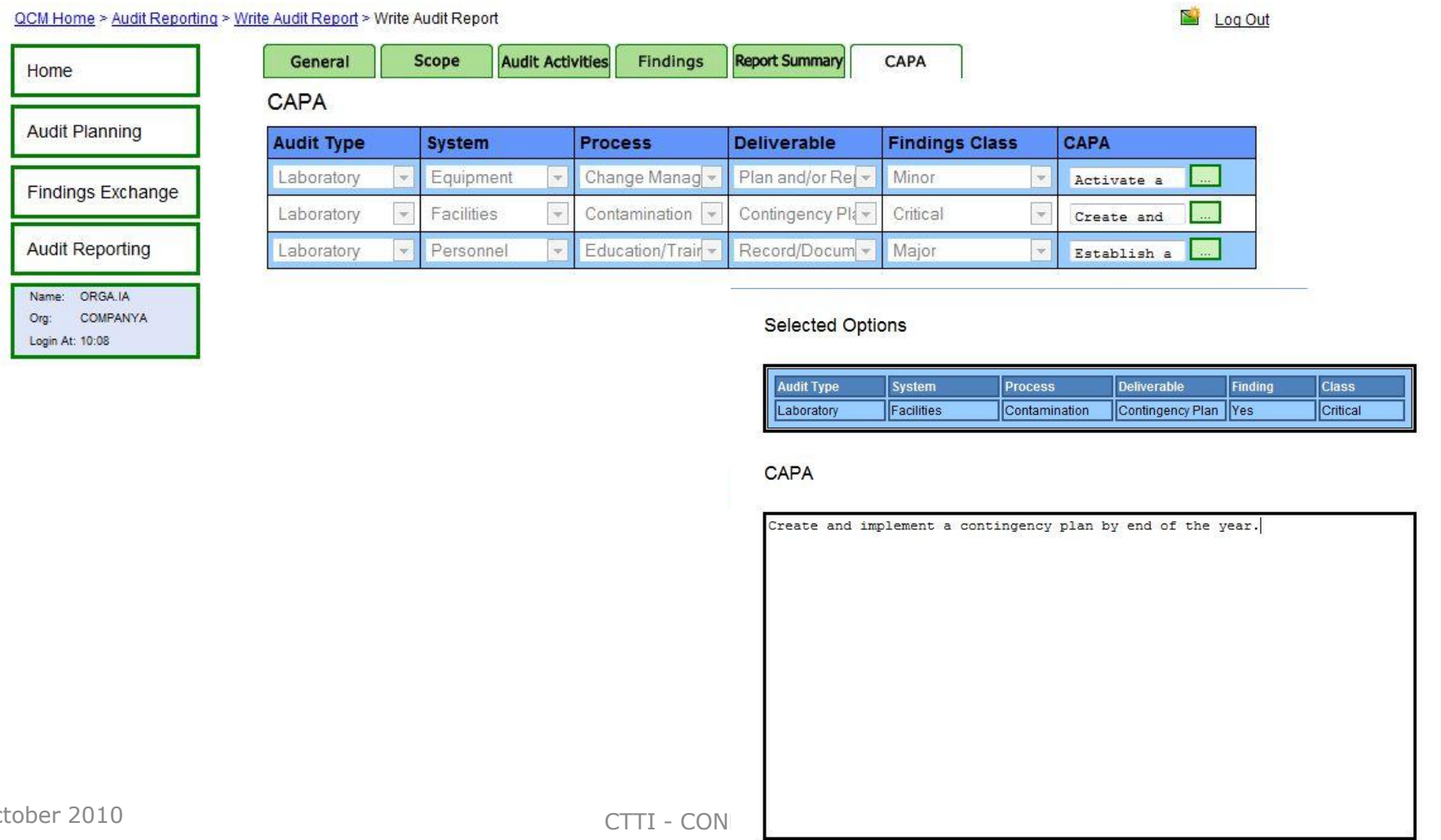
Writing reports is facilitated as a large number of the fields are pre-populated and the findings can be published to designated partners





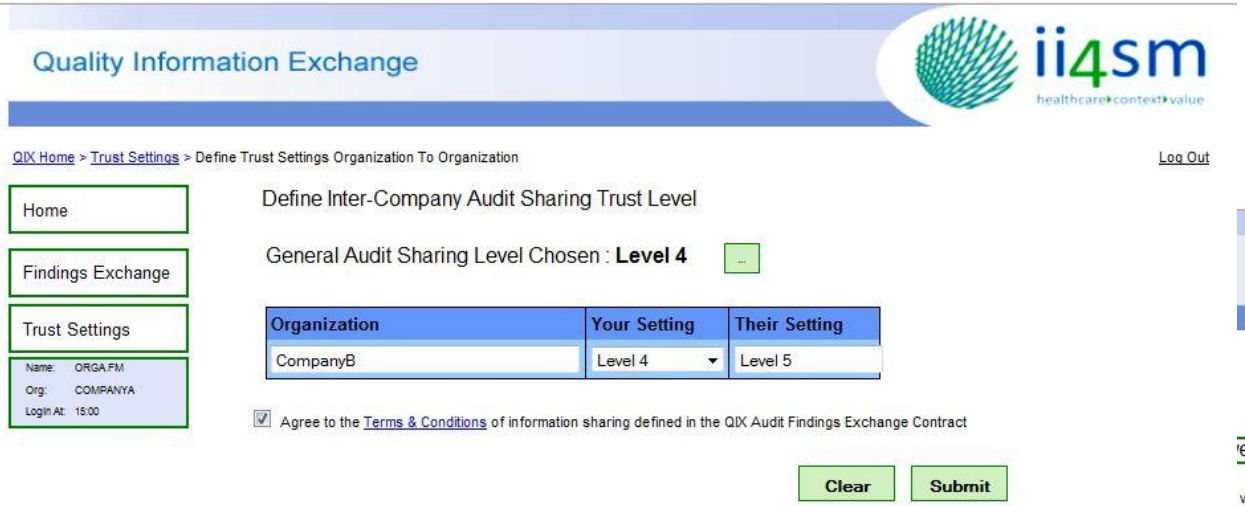
CAPA Management & Working with auditees

The findings matrix can be directly linked to CAPAs and mitigation actions with select access for auditees to propose edits for reports and CAPAs during the approval loop



Setting Trust Levels & Ensuring Confidentiality

Trust levels and role-based access ensure that only anonymous data specifically designated for release can be seen by others and access is actively granted



	Description
0	Use this as the default level if you do not wish to share any information * All information only for internal company users * Data can be used only by ii4sm for anonymized aggregated benchmarking and analysis
1	At Level 1 only the following information will be exposed: * Audit Location, Country & City * Audit Category
2	At Level 2 information from lower levels and the following information will be shared: * Audit Type * Audit Objective
3	At Level 3 information from lower levels and the following information will be shared: * Audit Report Summary * Do Findings Exist in the Audit Report
4	At Level 4 information from lower levels and the following information will be shared: * Audit Checklist Colums (Type, System, Processes, Deliverables) * Audit Report Columns (Findings, Class) Only finding rows where Proprietary = No
5	At Level 5 information from lower levels and the following information will be shared: * Audit Report Columns (Comment) Only finding rows where Proprietary = No

Confidentiality Concerns

Confidentiality concerns can also be addressed by segmenting data into individual activities that do not compromise the auditee or the auditor and by anonymising it

	Example Audit Process						
Type of Audit Examples	Request	Approval	Schedule Planning	Auditor Selection	Prepare	Conduct	Report
Clinical Trial Centre							
Affiliates & Marketing							
Laboratory							
CRO							
Pharmacovigilance							
Due Dilligence							
Mock Inspections							
Investigations							
Pre-Inspection Visits							
CTC Compliance (CRO)							
Other							

Confidentiality according to preference Confidentiality agreement required Confidential

Why would an organisation participate?

Organisations will actively share information if there are tangible benefits that overcome reservations about confidentiality or company-specific methods

- All participants can actively benefit from
  - Shared information that provides new perspective on internal data
  - Access to a pool of standardised and ‚credentialised' service provider and audit data
  - Analysis of trends, quality heat maps and warning flags for outliers

- This prototype is focused on GCP QA although the same principles apply for
  - Reports from monitoring visits or inspections
  - Pre-inspection visits and other quality data collection processes
  - Any other data source (e.g., QRM, ADAMON, study quality assessment data)

- Smaller organisations can manage their audit process
  - Without paying substantial license fees for COTS software
  - Can benefit from the larger scale of audit activity and share audit packages
  - Can improve the transparency and robustness of their processes

ii4sm

healthcare ▸ context ▸ value

International Institute for the Safety of Medicines Ltd.
Bollwerk-Promenade 5, CH-4051 Basel, Switzerland

Phone: +41 61 865 60 60
Fax: +41 61 865 60 61
Web: www.ii4sm.com