

CLINISYS LABORATORY SYSTEM

CLS UX COMPLIANCE & ACCESSIBILITY

DESIGN REQUIREMENTS

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Regulations define obligations. Research reveals user needs. Design reconciles the two. Validation provides evidence that both have been met.

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PURPOSE & SCOPE

CLS was built and sold exclusively in the United States. As Clinisys prepared to make CLS available to clients outside of the United States, and eventually the broader European market, no formalized accessibility, usability, or data-protection framework existed to guide that expansion. Requirements had historically been addressed reactively, on a case-by-case basis, rather than incorporated systematically into the design process.

This document translates applicable accessibility, usability, privacy, and security standards across the U.S. and U.K. markets into concrete UX design requirements for CLS.

Its purpose is to help Product, UX, Engineering, and QA identify compliance-related design considerations early enough to influence the experience rather than discovering them during implementation or release review.

The document is intended to function as a working tool during:

- discovery and workflow analysis
- wireframe and interaction design
- design review
- accessibility review
- engineering handoff
- implementation QA
- pre-release validation

It is not intended to replace formal legal, security, regulatory, or accessibility certification.

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DESIGN PHILOSOPHY

CLS should be designed so that accessibility, usability, security, and privacy are considered as part of the same user experience rather than as separate compliance activities.

Each area influences how users understand, navigate, and complete work in the system. A change intended to improve one area can create new problems in another. For example, a security control can add unnecessary friction, while a

highly efficient interface can still create accessibility barriers if it relies on color, dense layouts, or mouse-only interaction.

The design objective is therefore to support efficient laboratory work while maintaining accessibility, clarity, appropriate access to information, and protection of sensitive data.

Design reviews should consider these factors together so that issues are addressed during the design process rather than discovered late in development.

Accessibility

Design experiences that can be perceived, understood, navigated, and operated by users with diverse abilities and assistive technologies.

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APPLICABLE STANDARDS

Standards fall into four broad categories: accessibility, usability and ergonomics, data protection, and security.

Some apply primarily to one market. Others—particularly WCAG and ISO 9241—provide shared design foundations that allow CLS to establish a consistent experience across markets.

STANDARD	MARKET	CATEGORY	UX RELEVANCE
WCAG 2.2 AA	U.S. + U.K.	Accessibility	Provides the primary design criteria for perceivable, operable, understandable, and robust digital experiences.
Section 508	U.S.	Accessibility	Establishes accessibility requirements for U.S. federal technology and references WCAG-based criteria.
ADA	U.S.	Accessibility	Prohibits disability-based discrimination and influences expectations for accessible digital services.
Public Sector Bodies Accessibility Regulations 2018	U.K.	Accessibility	Requires covered public-sector websites and applications to meet accessibility requirements and maintain accessibility statements.
EN 301 549	U.K. / EU	Accessibility	European ICT accessibility standard incorporating WCAG requirements and additional technology-specific criteria.
European Accessibility Act	EU	Accessibility	Establishes accessibility obligations for specified products and services sold in the European market.

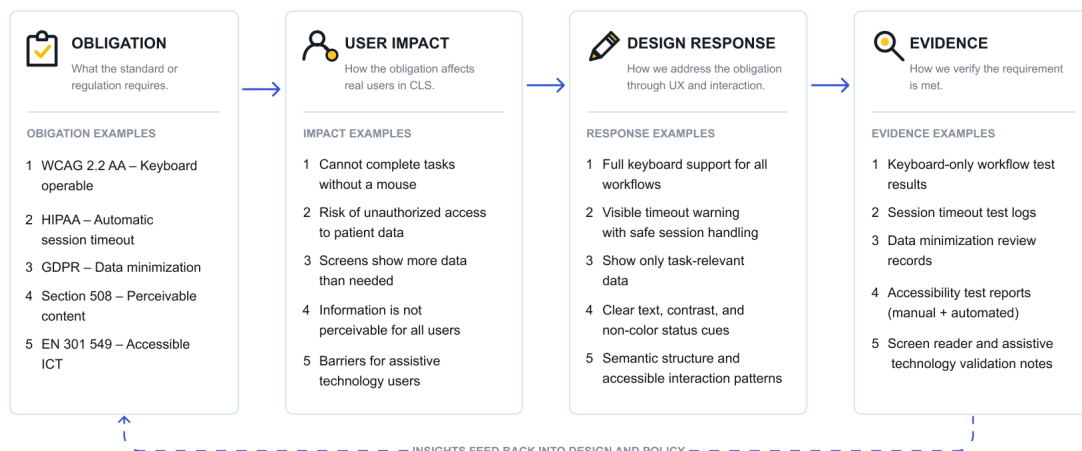
STANDARD	MARKET	CATEGORY	UX RELEVANCE
ISO 9241	U.S. + U.K.	Usability / Ergonomics	Provides human-system interaction principles covering effectiveness, efficiency, user needs, interaction quality, and ergonomics.
GDPR / UK GDPR	U.K. / EU	Data Protection	Influences transparency, consent, data minimization, access, and other user-facing treatment of personal information.
HIPAA	U.S.	Data Protection	Requires safeguards around protected health information, influencing access, visibility, session management, and auditability.
NIST guidance	U.S.	Security	Informs authentication, access control, identity, cybersecurity risk, and related interaction patterns.
Cyber Essentials / Plus	U.K.	Security	Establishes baseline cybersecurity controls relevant to authentication, access, configuration, and system protection.
ISO 27001	International	Security	Provides a broader information-security management framework that may inform product and organizational controls.

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TRANSLATING STANDARD INTO UX

Standards do not automatically determine interface design.

A regulatory statement must be translated into four things:



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ACCESSIBILITY REQUIREMENTS

Design Objective

Ensure CLS workflows can be perceived, understood, navigated, and operated by users with diverse visual, motor, cognitive, and assistive-technology needs.

ACC-001 — TEXT CONTRAST

REQUIREMENT

Text shall maintain sufficient contrast against its background.

MINIMUM TARGET

- 4.5:1 for normal text
- 3:1 for large text where permitted by WCAG
- applicable non-text contrast criteria for meaningful interface components

CONSIDERATIONS

- specimen statuses
- result flags
- disabled states
- table content
- secondary metadata
- warning messages
- toolbar controls

VALIDATION

Automated contrast check plus manual visual review.

ACC-002 — KEYBOARD OPERABILITY

All interactive functionality shall be operable without a mouse.

This includes:

- worklists
- menus
- filters
- tables
- dialogs
- tabs
- expandable regions
- result actions
- specimen workflows
- order entry
- reporting interfaces

Focus shall move in a logical sequence and remain visible.

VALIDATION

Keyboard-only task walkthrough.

ACC-003 — VISIBLE FOCUS

Keyboard focus shall be clearly distinguishable from hover, selection, and default states.

Focus indicators shall remain visible on all interactive controls, including compact toolbar actions and controls embedded in tables.

Avoid

- suppressing browser focus indicators without replacement
- color-only focus treatment
- focus states that disappear against adjacent content

ACC-004 — LOGICAL FOCUS ORDER

Focus order shall follow the visual and task sequence of the interface.

Users shall not be required to tab through unrelated controls before reaching the next logical task element.

When dialogs, menus, or overlays open, focus shall move to the newly active context and return appropriately when that context closes.

ACC-005 — FORMS AND LABELS

Every form control shall have a persistent, programmatically associated label.

Placeholder text shall not serve as the sole label.

Instructions shall appear before they are needed and remain available while the user completes the field.

Required fields shall be identified in a way that does not rely on color alone.

ACC-006 — ACCESSIBLE NAMES FOR CONTROLS

Buttons, links, icons, and interactive controls shall have clear accessible names that communicate their purpose.

Icon-only controls shall not depend solely on visual recognition.

Examples include:

- edit
- delete
- expand
- refresh
- filter
- save
- close
- more actions

ACC-007 — ERROR IDENTIFICATION

Errors shall:

- identify the affected field or control
- describe the problem in text
- provide corrective guidance where possible
- not rely on color alone
- be programmatically associated with the relevant field
- be announced appropriately to assistive technologies

GOOD

Collection date cannot be later than today's date.

POOR

Invalid input.

ACC-008 — ERROR PREVENTION

Where an action has significant consequences, the interface should help prevent accidental submission or irreversible changes.

Examples:

- finalizing results
- overriding clinical values
- deleting data
- releasing reports
- changing configuration

The level of confirmation should reflect the level of risk.

ACC-009 — NON-COLOR COMMUNICATION

Meaning shall never depend entirely on color.

CLS examples include:

- abnormal results
- urgency
- specimen status
- antimicrobial resistance indicators
- task completion
- warnings
- validation errors

Color may reinforce meaning but shall be paired with text, iconography, pattern, or another cue.

ACC-010 — DATA TABLES

Tables shall preserve semantic relationships between:

- headers
- rows
- columns
- values
- states
- available actions

This is especially important for CLS worklists and result grids, where users interpret multiple variables simultaneously.

Tables should support predictable keyboard navigation and appropriate screen-reader interpretation.

ACC-011 — TABLE INTERACTION

Interactive controls within tables shall be keyboard accessible and clearly identified.

Sorting, filtering, expanding rows, selecting records, and invoking row-level actions shall not require pointer interaction.

Users shall be able to determine:

- which column is sorted
- current sort direction
- whether rows are selected
- whether content is expanded
- whether filters are applied

ACC-012 — DYNAMIC CONTENT

Meaningful dynamic changes shall be communicated to assistive technologies where appropriate.

Examples:

- new tasks
- refreshed worklists
- save completion
- validation results
- status changes
- newly available results

Updates should not unnecessarily interrupt the user's current task.

ACC-013 — STATUS MESSAGES

Status messages that provide important feedback shall be available to assistive technologies without requiring users to move focus.

Examples:

- save successful
- record updated
- filter applied
- result posted
- background process completed

ACC-014 — TEXT RESIZE

Interfaces shall remain understandable and operable when text is resized up to 200%.

Essential content and controls shall not:

- overlap
- disappear
- become clipped
- require horizontal scrolling unnecessarily

ACC-015 — REFLOW AND ZOOM

At supported zoom levels and viewport sizes, content shall reflow without loss of information or functionality where technically appropriate.

For dense laboratory interfaces, exceptions should be limited to content that inherently requires two-dimensional presentation, such as complex data tables.

Even in those cases, controls and surrounding content must remain accessible.

ACC-016 — TARGET SIZE

Interactive targets shall provide sufficient size and spacing to reduce accidental activation.

Special attention should be given to:

- compact table controls
- icon-only actions
- row menus
- close buttons
- checkboxes
- high-frequency laboratory actions

ACC-017 — HEADINGS AND PAGE STRUCTURE

Pages shall use a clear and logical heading hierarchy.

Headings should describe the structure of the page rather than be used only for visual styling.

Users navigating with assistive technologies shall be able to understand the organization of:

- worklists
- forms
- result review screens
- dashboards
- settings
- reports

ACC-018 — LANDMARKS AND REGIONS

Major interface regions shall be programmatically identifiable where appropriate.

Examples:

- navigation
- main content
- search
- filters
- complementary information
- footer

Repeated page structures should use consistent landmarks.

ACC-019 — LINKS

Link text shall clearly describe the destination or action.

Avoid ambiguous labels such as:

- Click here
- More
- Learn more

When repeated link labels are necessary, surrounding context or accessible naming shall distinguish them.

ACC-020 — DIALOGS AND MODAL WINDOWS

Dialogs shall:

- receive focus when opened
- contain focus while active when appropriate
- provide a clear title
- expose close and cancel controls
- return focus to the triggering control when closed

Users shall not be able to accidentally interact with content behind a modal dialog.

ACC-021 — MENUS, POPOVERS, AND TOOLTIPS

Menus and popovers shall be keyboard accessible and dismissible.

Tooltips shall not contain information that is unavailable through another accessible method.

Critical instructions shall not be provided only through hover interaction.

ACC-022 — EXPANDABLE CONTENT

Expandable panels, accordions, and disclosure controls shall expose their expanded or collapsed state to assistive technologies.

The control shall clearly identify the content it reveals.

ACC-023 — DRAG-AND-DROP ALTERNATIVES

Any functionality implemented through drag and drop shall also provide a non-drag alternative.

Examples:

- reordering items
- moving entries
- arranging dashboard elements

Users with limited motor control or keyboard-only interaction must be able to perform the same task.

ACC-024 — MOTION AND ANIMATION

Animations shall not create unnecessary barriers or distraction.

Motion that is not essential should be reduced or removable when users indicate a preference for reduced motion.

Flashing content that could trigger seizures shall not be used.

ACC-025 — TIME LIMITS

Where workflows impose time limits, users shall receive appropriate warning and the ability to extend the session where security and policy permit.

This requirement must be balanced with HIPAA and organizational session-management requirements.

Timeout behavior shall not cause users to lose entered data without warning where avoidable.

ACC-026 — AUTHENTICATION ACCESSIBILITY

Authentication flows shall be accessible to users with disabilities.

Users shall not be required to complete inaccessible cognitive or visual challenges where accessible alternatives are available.

Password, MFA, and recovery interactions shall support:

- keyboard navigation
- screen readers
- clear instructions
- accessible error handling

ACC-027 — LANGUAGE

The primary language of each page shall be programmatically identified.

Changes in language within content should be identified where necessary for correct assistive-technology pronunciation.

This becomes increasingly important as CLS expands into additional markets.

ACC-028 — READING ORDER

Programmatic reading order shall match the intended visual and task sequence.

Layouts created using columns, cards, panels, or complex grids shall not produce a confusing reading order for screen-reader users.

ACC-029 — INSTRUCTIONS

Instructions shall not rely solely on sensory characteristics.

Avoid directions such as:

- click the red button
- select the icon on the right
- choose the field below

Instructions should identify controls by their name or function.

ACC-030 — HELP FOR COMPLEX INPUTS

Complex data-entry tasks shall provide accessible instructions, examples, or contextual help when users need them.

This is especially relevant to:

- specialized laboratory terminology
- coded values
- multi-field result entry
- complex filters
- specimen configuration

ACC-031 — CAPTIONS AND TRANSCRIPTS

If CLS includes instructional video, audio, training material, or embedded media, equivalent accessible alternatives shall be provided.

Depending on media type, this may include:

- captions
- transcripts
- audio description

ACC-032 — IMAGES AND NON-TEXT CONTENT

Meaningful images, diagrams, and icons shall have an appropriate text alternative.

Decorative images shall be hidden from assistive technologies where appropriate.

Complex diagrams should provide an equivalent description when the visual contains information necessary to complete a task.

ACC-033 — CONSISTENT IDENTIFICATION

Controls performing the same function across CLS shall use consistent labels, icons, and interaction behavior.

For example, the same action should not be labeled:

- Submit
- Save
- Complete

in different areas unless the actions are meaningfully different.

ACC-034 — CONSISTENT NAVIGATION

Repeated navigation mechanisms shall appear in a consistent relative order unless a workflow requires a meaningful exception.

Users should not have to relearn basic navigation when moving between laboratory disciplines.

ACC-035 — FOCUS NOT OBSCURED

Keyboard focus shall not be completely hidden by sticky headers, floating toolbars, dialogs, banners, or other overlapping interface elements.

When focus moves, the focused element should remain visible enough for users to identify their current position.

ACC-036 — ACCESSIBLE HELP AND SUPPORT

Help content, documentation, and support links required to complete a workflow shall be accessible through the same interaction methods as the product itself.

Accessibility problems shall not be shifted into inaccessible external documentation.

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ACCESSIBILITY RESEARCH CONSIDERATIONS

Accessibility review should not rely solely on automated scanning.

Representative workflows should be evaluated against realistic laboratory tasks.

Priority research scenarios include:

- navigating a worklist without a mouse
- entering specimen information
- reviewing microbiology results
- identifying abnormal or critical results
- completing forms containing validation errors
- navigating large data tables
- interacting with dialogs and overlays
- responding to changing system status

Where practical, research should include users of assistive technologies rather than relying exclusively on simulated accessibility testing.

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USABILITY REQUIREMENTS

Design Objective

Enable laboratory users to perform complex, repetitive, and safety-sensitive tasks with minimal unnecessary cognitive or interaction burden.

USA-001 — CONSISTENCY

Navigation, terminology, controls, and interaction behavior shall remain consistent across CLS disciplines.

Users moving between Microbiology, Clinical Pathology, Environmental, and other supported workflows should not have to relearn fundamental interaction patterns.

USA-002 — SYSTEM STATUS

The system shall communicate its current state.

Examples include:

- loading
- saving
- saved
- refreshing
- processing
- completed
- failed
- disconnected
- synchronized

Users should never have to guess whether an action succeeded.

USA-003 — CONTEXT PRESERVATION

Where appropriate, CLS should preserve:

- filters
- sort order
- current specimen
- worklist position
- selected tab
- relevant search criteria

Users performing multi-step laboratory tasks should not be forced to reconstruct context unnecessarily.

USA-004 — COGNITIVE LOAD

Screens shall prioritize information according to the user's immediate task.

Secondary information should remain available without competing visually with decision-critical information.

USA-005 — ERROR PREVENTION

The design should prevent predictable errors before relying on error messages.

Examples:

- constrain invalid date ranges
- prevent incompatible selections
- distinguish irreversible actions
- provide defaults based on workflow context
- disable unavailable actions when the reason is understandable

USA-006 — DESTRUCTIVE ACTIONS

Actions with significant or difficult-to-reverse consequences shall require an appropriate safeguard.

Examples may include:

- deleting data
- cancelling finalized work
- overriding a result
- changing critical configuration
- releasing or invalidating information

Confirmation should be proportional to risk.

Routine reversible actions should not be interrupted unnecessarily.

USA-007 — RECOGNITION OVER RECALL

Users should not have to remember information that the system can reasonably retain or display.

This is particularly important during multi-step workflows involving:

- accession numbers
- organism identification
- result context
- specimen information
- location
- patient details
- pending actions

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SECURITY-ADJACENT UX REQUIREMENTS

Design Objective

Integrate security controls into normal workflows without unnecessary ambiguity or friction.

SEC-001 — AUTHENTICATION

Authentication interfaces shall clearly communicate:

- required credentials
- MFA requirements
- authentication failures
- account state
- recovery paths

Security messages should help legitimate users recover without revealing information useful to an attacker.

SEC-002 — ROLE-BASED ACCESS

CLS shall expose only information and actions appropriate to the user's authorized role.

Where users lack permission, the design should distinguish appropriately between:

- unavailable action
- unavailable data
- restricted action requiring escalation

Hiding controls should not be treated as the underlying security mechanism; authorization must also be enforced technically.

SEC-003 — SESSION STATE

Users shall receive appropriate warning before an automatic session timeout where policy permits.

Where protected information is visible, the system shall prevent indefinite unattended access.

SEC-004 — SECURITY MESSAGING

Security errors shall use plain language and avoid exposing:

- stack traces
- implementation details
- internal paths
- database information
- protected health information
- unnecessary account information

PRIVACY & DATA PROTECTION REQUIREMENTS

Design Objective

Expose and collect only the information required for a legitimate workflow and make privacy-related interactions understandable.

PRI-001 — DATA MINIMIZATION

Each screen should display only the patient or personal information necessary for the user's task.

This is a UX consideration as well as a backend data-governance principle.

PRI-002 — APPROPRIATE DISCLOSURE

Sensitive data should not appear unnecessarily in:

- notifications
- confirmation messages
- search results
- global navigation
- browser-facing titles
- error messages

PRI-003 — CONSENT

Where consent is required, the interface shall communicate:

- what the user is agreeing to
- why information is required
- how it will be used
- relevant consequences or choices

Consent should not be buried in unrelated content.

PRI-004 — DATA RIGHTS

Where applicable to the deployed market and workflow, UX shall support mechanisms associated with lawful access, correction, export, or deletion processes.

PRI-005 — AUDITABILITY

Actions involving sensitive or protected records shall generate the audit information required by the applicable technical and organizational policy.

The user interface should clearly differentiate actions that are recorded or consequential where that knowledge materially affects user decisions.

DESIGN PATTERNS AND ANTI-PATTERNS

PREFER	AVOID
Persistent labels	Placeholder-only labels
Text + icon + color	Color-only status
Visible keyboard focus	Suppressed focus outlines
Specific corrective errors	“Invalid value”
Semantic tables	Visually simulated tables
Risk-based confirmations	Confirming every routine action
Role-relevant information	Exposing all available data
Plain-language security messaging	Technical system errors
Persistent workflow context	Resetting filters after navigation
Visible system status	Silent background processing
Persistent labels	Placeholder-only labels
Text + icon + color	Color-only status
Visible keyboard focus	Suppressed focus outlines

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UX RESEARCH QUESTIONS

Compliance review should include behavioral questions, not simply technical checks.

Accessibility

- Can users complete critical tasks without a mouse?
- Can users understand state without relying on color?
- Can assistive technologies interpret worklists and data tables?
- Can users recover from validation errors?

Usability

- Where do users hesitate?
- Which tasks generate repeated errors?
- What information must remain visible throughout a workflow?
- Which controls introduce unnecessary interaction cost?

Security

- Do users understand authentication and permission states?
- Do security controls cause unsafe workarounds?
- Can users recover from timeout or authentication failure?

Privacy

- Is sensitive information visible where it is not required?
- Do users understand privacy-related choices?
- Does the interface expose more information than the workflow requires?

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VALIDATION MODEL

Compliance should be evaluated using multiple forms of evidence.

DESIGN CHANGE	VALIDATION OUTCOME
Contrast	Automated + manual review
Keyboard access	Keyboard walkthrough
Screen-reader behavior	Assistive-technology evaluation
Workflow usability	Moderated usability testing
Error prevention	Scenario testing
Information comprehension	Research / usability testing
Authentication UX	Workflow evaluation
Permission behavior	Role-based QA
Session timeout	Functional QA
Audit trail	Engineering / QA verification
Data minimization	UX + privacy review

Automated accessibility tools should be treated as one input, not proof of accessibility.

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DESIGN REVIEW CHECKPOINTS

Compliance is reviewed at two primary UX checkpoints.

CHECKPOINT 1 — STRUCTURAL REVIEW

Timing: Wireframe / interaction-design stage.

Review:

- navigation
- hierarchy
- keyboard interaction
- data-table structure
- labeling
- workflow context
- error prevention
- data minimization
- role visibility

Issues found here should be corrected before high-fidelity design whenever practical.

CHECKPOINT 2 — VISUAL & INTERACTION REVIEW

Timing: Before final design handoff.

Review:

- contrast
- focus treatment
- interaction states
- error presentation
- typography
- target sizing
- status communication
- final labels
- responsive behavior

Implementation-dependent controls move into engineering and QA verification.

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OWNERSHIP

Owns:

- UX interpretation of requirements
- accessibility design review
- workflow usability
- interaction patterns
- research validation
- design-related issue tracking

Engineering

Owns implementation-dependent requirements including:

- authorization enforcement
- session management
- authentication implementation
- audit logging
- semantic implementation
- secure data handling

QA

Verifies implementation against documented requirements and regression criteria.

Security / Compliance

Provides interpretation and approval where requirements depend on organizational policy, certification, law, or formal regulatory interpretation.

Open items should be logged and tracked as design or technical debt rather than remaining informal review comments.

PRE-RELEASE CHECKLIST

Accessibility

- ☐ ACC-001 Contrast verified
- ☐ ACC-002 Keyboard workflows verified
- ☐ ACC-003 Focus visible throughout
- ☐ ACC-004 Forms correctly labeled
- ☐ ACC-005 Errors accessible and corrective
- ☐ ACC-006 Status does not rely on color
- ☐ ACC-007 Tables maintain semantic relationships
- ☐ ACC-008 Dynamic updates appropriately communicated
- ☐ ACC-009 Zoom / resize reviewed
- ☐ ACC-010 Interactive target size reviewed

Usability

- ☐ Navigation terminology consistent
- ☐ System status visible
- ☐ Workflow context preserved
- ☐ Cognitive load reviewed
- ☐ Preventable errors addressed
- ☐ High-risk actions appropriately safeguarded
- ☐ Repeated information does not depend on memory

Privacy

- ☐ Screens follow data-minimization principles
- ☐ Sensitive data does not appear unnecessarily
- ☐ Consent interactions reviewed where applicable
- ☐ Market-specific privacy workflows supported
- ☐ Protected-record activity auditable

Security

- ☐ Authentication UX reviewed
- ☐ Role-based visibility verified
- ☐ Unauthorized actions blocked
- ☐ Session behavior verified
- ☐ Security errors contain no sensitive information

U.K. / EU Readiness

- ☐ U.K. accessibility obligations reviewed for applicable deployments
- ☐ EN 301 549 alignment assessed
- ☐ Accessibility statement requirement determined
- ☐ European expansion requirements reviewed before market entry
- ☐ Applicable data-protection requirements incorporated into relevant workflows

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TRACEABILITY EXAMPLE

ID	SOURCE	UX REQUIREMENT	VALIDATION	OWNER
ACC-002	WCAG	Critical workflows operable by keyboard	Keyboard task test	UX + QA
ACC-006	WCAG	Status not communicated by color alone	Visual/accessibility review	UX
USA-003	ISO 9241	Preserve task context	Workflow usability study	UX
PRI-001	GDPR / privacy principles	Minimize exposed personal data	UX/privacy review	UX + Compliance
SEC-002	NIST / security policy	Role-appropriate actions and information	Role-based functional test	Engineering + QA