2024.1 Patient Screening

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  - **Fixed diagnosis codes incorrectly matching when calculating cancer episode diagnoses associations.**
  - **Fixed inaccurate tooltip and Help documentation for the description of Total Eligible Patients under Disease Sites in the Trial Portfolio.**

Enhancements

Updated product information

The pre-screening, patient querying, and cohort building application offered by Inteliquet™ has been renamed from OncWeb™ to Patient Screening. Inteliquet Patient Screening has been updated with the following:

- New logo
- New login, security, and password reset screens
- New banner color and size
- Profile icon in the banner has been replaced with the signed in user's username.

Display qualifying patient data in results for Inteliquery™ and Advanced Inteliquery

A Matched Criteria view has been added for the patient list results from Inteliquery and Advanced Inteliquery. Matched Criteria displays the data that matched each patient to each of the query's criteria.

The structure of the Matched Criteria view reflects the structure of the query using nested columns. Inteliquery results in Matched Criteria are displayed with the Criteria as the top-level column and component type specific columns under those. A dvanced Inteliquery results in Matched Criteria are displayed with criteria as the top-level of columns, components nested in the second level, and component type specific columns under their components.

Alerts overhaul

Alerts and notifications for Patient Screening have been overhauled including new Global Alerts, replacements for patient specific alerts, and team management functionality for site administrators.

Changes to Alert Settings in the user profile

- Alerts have been separated into two categories: Global and By Patient.
- Global screen in Alert Settings displays the Global alerts and how the signed in user has them configured.
- By Patient screen in Alert Settings displays all patient specific alerts configured by the signed in user.

Changes to global alerts

- Patient Recruitment Alerts have been removed.
- The following global alerts were added:
  - Query Result Changes: The user can select queries for this alert to track and Patient Screening will send them a notification when patients are added or removed from the results of those queries overnight.
  - Recruitment Status Changes by Provider: The user can select providers for this alert to track and Patient Screening will send them a notification when a patient of one of those providers has their recruitment status changed for one of the selected trials.
    The user can add multiple providers to this alert. The user can select multiple trials for each provider.
  - Next Patient Visits by Provider: The user can select providers for this alert to track and Patient Screening will send them a notification when a patient of one of those providers with any recruitment status for one of the selected trials has an upcoming visit matching one of the selected next visit types.
    The user can add multiple providers to this alert. The user can add multiple notifications for each provider to be notified in advance of any matching visits.
    - Example: Your alert is configured to send a notification 5 days before and 0 days before any patient has an Office Visit with Dr. Rivers and that patient has a recruitment status for trial NCT0123456. Jane Doe (patient) has an upcoming Office Visit (matching visit type) with their provider, Dr. Rivers in 7 days. Jane Doe has a recruitment status of Watch for trial NCT0123456. You will receive a notification in 2 days and in 7 days regarding Jane Doe's Office Visit.

Changes to patient specific alerts

- Alerts for specific patients has been removed from the Patient Status & Notes dialog.
- Alerts for specific patients have a new dialog: Alert Settings: By Patient that is available through Alert Settings, Patient Chart, or Patient Criteria and Patient Trials within Inteliscreen.
- The following alerts have been added:
  - Event Date: Patient Screening will send the user a notification on the configured date and any advance notification dates for the alert.
  - Next Visit: The user can select Next Visit types for Patient Screening to track and send them a notification when the selected patient has an upcoming visit of those types.
  - Trial Recruitment Status Change: The user can select clinical trials for Patient Screening to track and send them a notification when the selected patient's Recruitment Status changes to one of the selected statuses for any of the selected trials.
  - Clinical Alert: The user can select a query for this alert to track and Patient Screening will send them a notification if the selected patient matches the query overnight.

Team management for site administrators

Site administrators have permissions to view and edit most alerts for site users (but not other administrators) through the Team Alerts tab in both the Global and By Patient pages of Alert Settings. Administrators can view and edit any site user's alerts for patients within a patient specific context, such as Patient Chart.

- Site administrators see a tabbed view within Alert Settings for both Global and By Patient alerts. Those tabs are:
  - My Alerts: alerts configured by the signed in administrator are displayed.
  - Team Alerts: alerts configured by all site users are displayed. Administrators cannot see alerts configured by other admins.
- Site administrators have the following additional functionality:
  - Add, edit, and remove Global and By Patient alerts for all site users.
    - Some alert types are not editable by administrators like Query Result Changes for Global and Clinical Alert for By Patient alerts.
  - Opt-in to receive a notification if a specific user changes their global alerts or their alerts for a specific patient.
  - Opt-in to receive the same notification as a user for any of that user's specific global alerts or for that user's alerts for a specific patient.

Chart review project flow

Patient Screening has added a flow to support chart review projects at our sites. Chart review projects processed through IQVIA Life Sciences can take advantage of reduced complexity when communicating necessary information between sites, Inteliquet, IQVIA Life Sciences, and the project's sponsor. Sites can enter the data extraction variables for each patient into an EDC project shared with IQVIA Life Sciences then utilize the new integrated workflow between Patient Screening and Feasibility Tool to send Life Sciences the mapping IQVIA Life Sciences needs to complete the chart review project.

1. The site's Primary Chart Review Manager collaborates with their Inteliquet Engagement Specialist and IQVIA Life Sciences before the chart review project officially kicks off to set up a shared EDC project and ensure the correct team members have access.
2. IQVIA Life Sciences can submit their Feasibility Tool query criteria to any site and Patient Screening creates a Chart Review patient list for that site's designated Primary Chart Review Manager.
   a. The site's Primary Chart Review Manager may also create Chart Review patient lists manually by entering a list of patient identifiers as if they were creating any other patient list.
3. The site's Primary Chart Review Manager collaborates with their Inteliquet Engagement Specialist to manage assignments for the chart review project.
4. The assigned team members working on the chart review create patient records in the shared EDC project and paste the generated EDC IDs into Patient Screening through the External ID link.
5. When all patients are completed, the Primary Chart Review Manager submits the Chart Review patient list to IQVIA Life Sciences in Patient Screening.
   a. Submitting the Chart Review patient list securely sends IQVIA Life Sciences a mapping for each patient between their Inteliquet Screening ID and the External ID. Until IQVIA Life Sciences receives this mapping, they cannot complete the chart review, but they have access to the patient records in the shared EDC project.

Progression tracking and task management in Chart Review patient lists

- Each patient within a Chart Review patient list can be marked as status Incomplete, In Progress, or Complete.
- The Patient Lists module landing page displays a progress bar and the number of patients with the Complete status out of the total patient count for quick reference.

Primary Chart Review Manager

Each facility can have a single user or administrator designated as the Primary Chart Review Manager. This individual has special permissions related to chart review projects and their account is required for submission of a completed chart review. This designation is maintained in User Administration and can be changed to another user or administrator by a site administrator. Coordinate with your Inteliquet Engagement Specialist so they are aware who the designated Primary Chart Review Manager at your facility is.
Only a facility's Primary Chart Review Manager can perform the following actions:

- Create and share a Chart Review patient list manually.
- Receive and initially share an automated Chart Review patient list. Any user can Share a Chart Review patient list once they have access. The Primary Chart Review Manager is required to initially coordinate sharing Chart Review patient lists with the correct team members.

- **Submit a Chart Review patient list.**

Expandable text box for component description in Clinical Trial Editor

The description text box for components in Clinical Trial Editor has an Expand button.

Search implemented for Disease Site field in Clinical Trial Editor > Info

The Disease Site Field under Clinical Trial Editor > Info can be used to search for and select a disease site instead of requiring manual entry.

Localization workflow

Patient Screening supports a workflow for approving and implementing changes to the User Interface for language localization purposes. Facilities that want to request localization changes for the next version of Patient Screening should follow the below process:

1. In the KodiakApi directory, locate the (locale).json file. (locale) is a placeholder for your locale code. For example, USA based facilities would reference the KodiakApi/en-us.json file.
2. Edit the text strings for any UI strings your facility wants to change.
3. Submit the edited (locale).json file to Inteliquet for review.

More information for this process is provided in the Operating Procedure Manual - Patient Screening.

Bug Fixes

Summary

Item	DevOps IDs	Name
1	5023	Fixed queries with a Visits component in Inteliquery failing to return results due to timing out.
2	5163	Fixed trials with stage IV data returning fewer potential patients than expected.
3	5164 6213	Fixed some patients not being marked with the Is Metastatic flag despite having a stage IV cancer diagnosis.
4	5168	Fixed trials failing to run when they contained a Diagnostics - Lab component with the Results Type of Abnormal Results and a lower or upper limit configured.
5	6198	Fixed an error referencing a missing key that would sometimes display when attempting to open a trial in Clinical Trial Editor.
6	6238 6500	Fixed an error when attempting to sort the selection check box column in the category editing screen of Category Manager.
7	6266 6660	Fixed the Locations button in Site Manager failing to direct the user to the locations screen.
8	6269 6485	Fixed an error in the Home Page when no clinical trials were defined in Patient Screening.
9	6270	Fixed an error message when a trial's Run or Get Counts process timed out in Clinical Trial Editor.
10	6279 6495	Fixed an error in the Home Page when the Patients by Provider widget attempted to load while only one site was set as Is Clinical Trial Site.
11	6499	Fixed an issue with Japanese language characters in downloaded reports being corrupted.

12	6751	Fixed selected values in components for queries accessed through the My Patient Queries widget displaying as empty rows.
13	6752	Fixed the Onset date for diagnoses in Patient Chart changing to adjust for time zones.
14	6809	Fixed diagnosis codes incorrectly matching when calculating cancer episode diagnoses associations.
15	6498	Fixed inaccurate tooltip and Help documentation for the description of Total Eligible Patients under Disease Sites in the Trial Portfolio.

Fixed queries with a Visits component in Inteliquery failing to return results due to timing out.

1	ID: 5023

Queries that included a Visits component in Inteliquery were timing out and failing to return results. This issue has been resolved.

Queries with Visits components return results.

Fixed trials with stage IV data returning fewer potential patients than expected.

2	ID: 5163

Trials in Inteliscreen were not displaying the expected number of potential patients when they included stage IV data. This issue has been resolved.

Trials including patients with stage IV cancer diagnoses display the expected number of potential patients.

Fixed some patients not being marked with the Is Metastatic flag despite having a stage IV cancer diagnosis.

3	ID: 5164
	ID: 6213

 Patients with stage IV cancer diagnoses were not always being marked with the Is Metastatic flag. This issue has been resolved.

All patients with a stage IV cancer diagnosis are marked with the Is Metastatic flag.

Fixed trials failing to run when they contained a Diagnostics - Lab component with the Results Type of Abnormal Results and a lower or upper limit configured.

4	ID: 5168

Trials containing a Diagnostics - Lab component with the Results Type of Abnormal Results and a lower or upper limit configured were failing to run. This issue has been resolved.

Trials with Diagnostics - Lab components return results regardless of the selected Results Type.

Fixed an error referencing a missing key that would sometimes display when attempting to open a trial in Clinical Trial Editor.

5	ID: **6198**

Attempting to open some trials in Clinical Trial Editor would result in an error that referenced a missing key. This issue has been resolved.

Opening a trial in Clinical Trial Editor does not result in an error.

Fixed an error when attempting to sort the selection check box column in the category editing screen of Category Manager.

6	ID: **6238** ID: **6500**

Attempting to sort concepts using the column header of the selection check box column in the available table of the category editing screen of Category Manager would result in an error. This issue has been resolved.

Clicking the column header for the selection check box column does not result in any action. Clicking the column header for the Concept column sorts the displayed concepts.

Fixed the Locations button in Site Manager failing to direct the user to the locations screen.

7	ID: **6266** ID: **6660**

Clicking the Locations button in Site Manager would not result in any action. This issue has been resolved.

Clicking the Locations button in Site Manager navigates the user to the locations screen in Site Manager.

Fixed an error in the Home Page when no clinical trials were defined in Patient Screening.

8	ID: **6269** ID: **6485**

If a facility did not have any trials defined in Patient Screening, then an error message would display in the Home Page. This issue has been resolved.

The Home Page does not display an error and the My Trials widget displays no information if the facility does not have any trials defined.

Fixed an error message when a trial's Run or Get Counts process timed out in Clinical Trial Editor.

9	ID: **6270**

Trial queries would sometimes time out when a Run or Get Counts process was initiated in Clinical Trial Editor. This issue has been resolved.

The Run and Get Counts processes do not result in a time out error and results are returned.

Fixed an error in the Home Page when the Patients by Provider widget attempted to load while only one site was set as Is Clinical Trial Site.

10	ID: **6279** ID: **6495**

If only one site was set as Is Clinical Trial Site then the Patients by Provider widget would fail to load and display an error message. This issue has been resolved.

The Patients by Provider widget displays no information and does not display an error if only one site is set as a clinical trial site.

Fixed an issue with Japanese language characters in downloaded reports being corrupted.

11	ID: **6499**

The downloaded report in Trial Portfolio was displaying Japanese characters as corrupted. This issue has been resolved.

Japanese characters in the downloaded report in Trial Portfolio display correctly.

Fixed selected values in components for queries accessed through the My Patient Queries widget displaying as empty rows.

12	ID: **6751**

The selected values in components for queries accessed through the My Patient Queries widget were displaying as empty rows. This issue has been resolved.

The selected values for components in queries accessed through the My Patient Queries widget display normally.

Fixed the Onset date for diagnoses in Patient Chart changing to adjust for time zones.

13	ID: **6752**

The Onset date for diagnoses in Patient Chart was changing to adjust for time zones. This issue has been resolved.

Onset date for diagnoses in Patient Chart do not adjust for time zones.

Fixed diagnosis codes incorrectly matching when calculating cancer episode diagnoses associations.

14	ID: **6809**

Diagnoses codes were incorrectly matching when calculating cancer episode diagnoses associations. This resulted in different results when querying for patients with the Cancer Episode component vs the Diagnosis component. This issue has been resolved.

Diagnoses codes are correctly matched when calculating cancer episode diagnoses associations. Querying the same ICD10 code in a Cancer Episode component returns the same patients as using a Diagnosis component.

Fixed inaccurate tooltip and Help documentation for the description of Total Eligible Patients under Disease Sites in the Trial Portfolio.

15	ID: 6498

The tooltip and Help documentation for the Total Eligible Patients field under Disease Sites in the Trial Portfolio incorrectly claimed that patients are eligible if they are "alive, have a cancer diagnosis, and was contacted in the last 18 months." The correct description is that patients are eligible if they are alive. Patients do not need a cancer diagnosis or recent contact to be considered eligible. This issue has been resolved.

The tooltip and help documentation for the Total Eligible Patients field under Disease Sites in the Trial Portfolio display an accurate description.