



ALZ-NET Data Compliance Training

Course Topic: Data & Query Resolution

Course Overview

In this session, you will learn:

- The importance of timely data entry and query resolution.
- How to efficiently navigate and resolve data queries assigned to your site.
- Tips to help your site stay on track of data entry and management.

QUICK LINKS

[Medidata Rave Application](#)

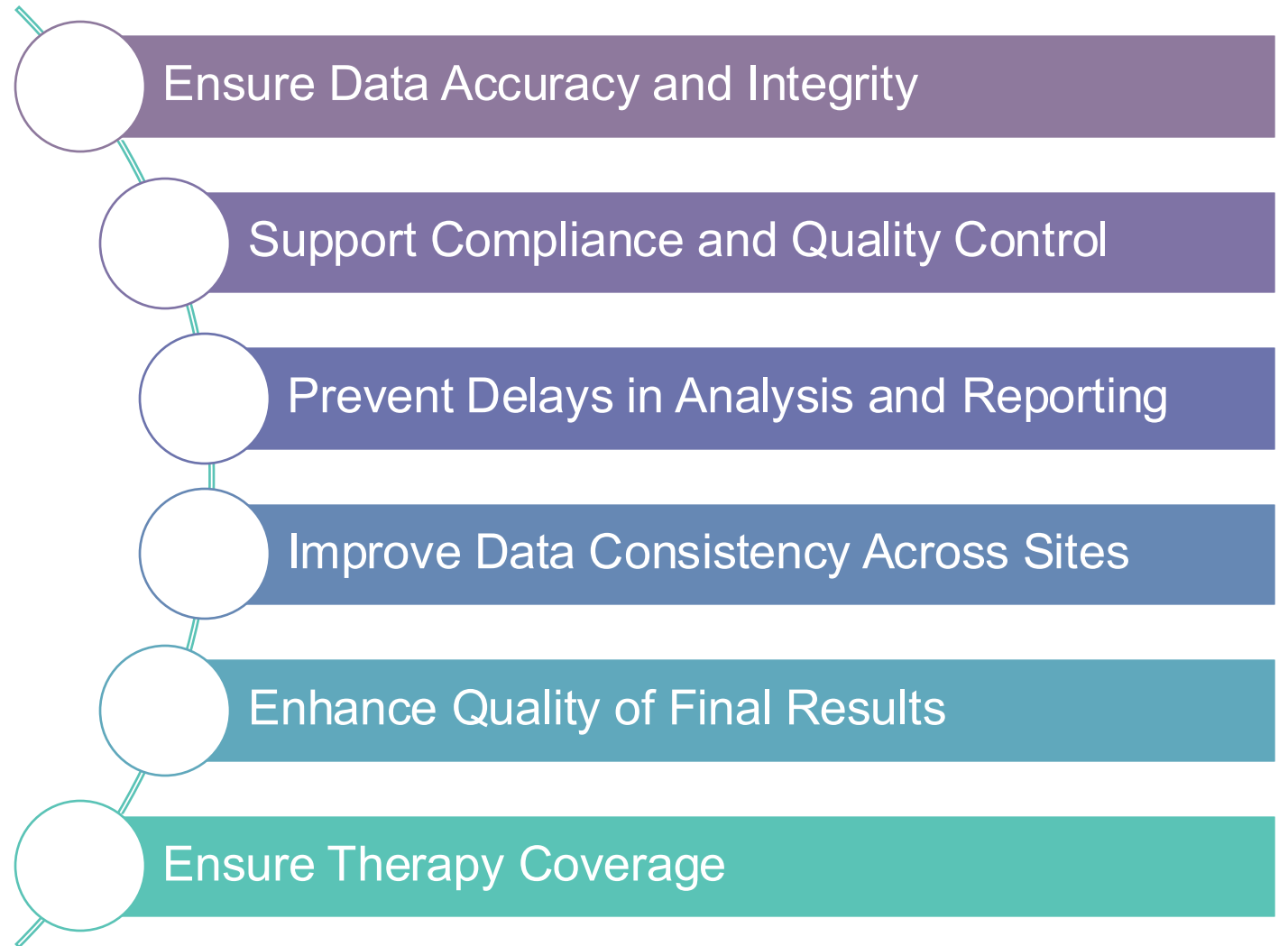
[Full Medidata Rave Training](#)

[Baseline CRF Packet](#)

[Follow-up CRF Packet](#)

[eCRF Training](#)

Your site's timely responses to ALZ-NET data queries are important to:



ALZ-NET Folders in Medidata Rave



Patient's Case ID #

Auto populated from patient registration data

Open *Baseline* folder, and complete forms in order, starting with *Baseline Reporting Period and Patient Status*.

must complete within 30 days of registration

Open applicable folder when patient is eligible for reporting period. Only report what occurred during the time period.




must complete within 30 days of reporting period end date.

Subject level folders can be completed at any time and are not tied to a specific time point. Adverse Events/ARIA

Adverse Events ***must be reported as soon as site is made aware**.









































****TRIAD Submission Log is auto-populated based on what has been submitted in TRIAD****

Understanding Icons in Medidata Rave

Common Icons	Site Action Required
 Complete	All data and queries resolved. No action required.
 Query Open	Question about submitted data from ALZ-NET DM Team. Requires site response within 30 days of receipt.
 Overdue	Form was not submitted within 30 days. Complete as soon as possible.

Click on the **Icon Key** button to view a list of all Medidata Rave icons.

Icon Key

-  Site
-  Studies
-  Study
-  Patient
-  Patient in doubt
-  Form
-  Site Group
-  Home
-  Comments
-  Edit
-  Study Status Deferred
-  Folder not available to the user
-  Task Summary Pop Up
-  Requires Coder Coding
-  Never Touched
-  Complete
-  Locked
-  Entry Lock
-  Not Conformant
-  Inactive
-  Overdue
-  Sticky Notes
-  Data Changed
-  Protocol Deviation
-  Site Status Deferred
-  Add Marking
-  Folder
-  Incomplete
-  Requires Verification
-  Requires Review
-  Query Open
-  Answered Query
-  Requires Coding
-  Requires Signature
-  Out of Range High
-  Out of Range Low
-  Requires Translation
-  Requires First Pass DDE
-  Requires Second Pass DDE
-  Requires Reconciliation DDE

Task Summary Tab

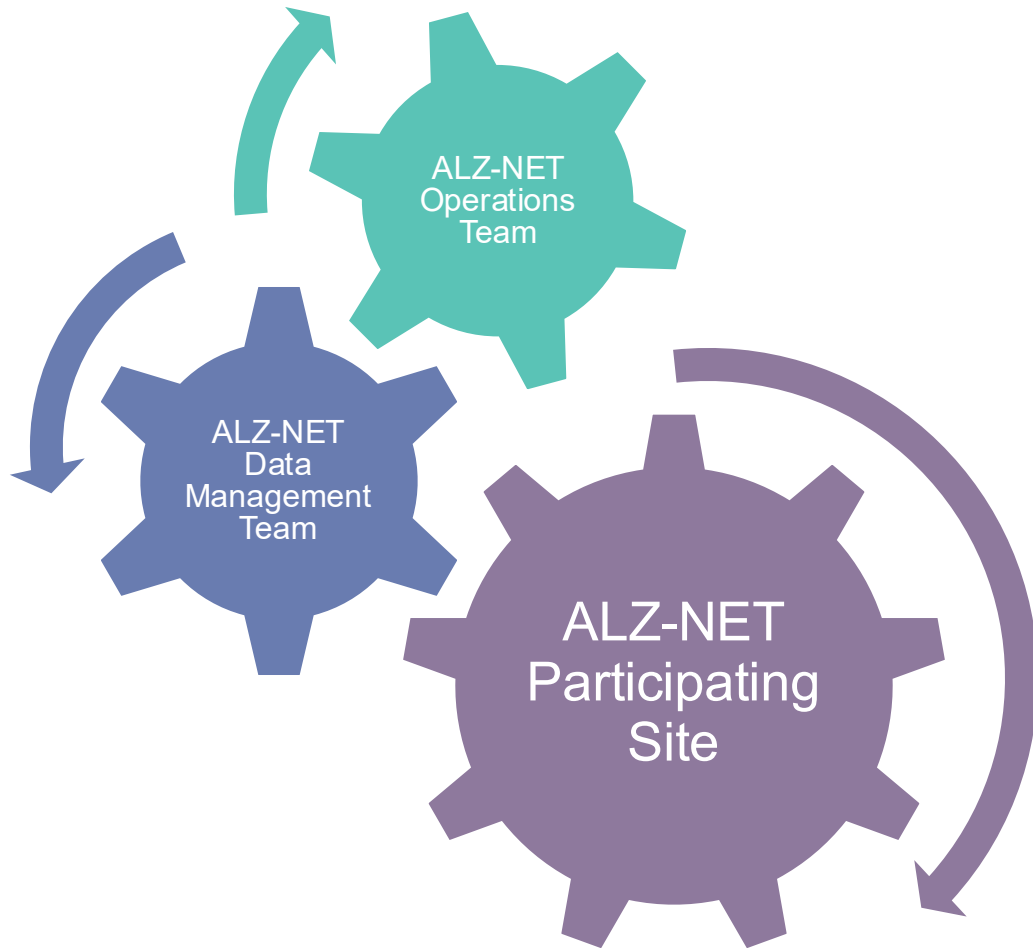
▼ Task Summary: Site

Click the Task Summary arrow to view clickable links to all outstanding queries and overdue forms by patient.

Task Summary: Site		Patients
▶ Requiring Signature		20
▶ NonConformant Data		58
▼ Open Queries		337
0909		
1010		
1111		
1040 - Open Queries		
Patient	Page	
1535-SD-29	Baseline-Baseline Novel Therapy - Brexpiprazole	
1535-SD-29	6 Month Follow-Up 01 Jun 2000-Follow-up Novel Therapy Administration YN	
1535-SD-29	6 Month Follow-Up 01 Jun 2000-Follow-up Novel Therapy - Brexpiprazole	
1535-SD-29	12 Month Follow-Up 31 Dec 2000-Follow-up Novel Therapy Administration YN	
1535-SD-30	Clinical Events-Clinical Events	
1548_AFR_001	Concomitant Medications-Concomitant Medications	
1548_AFR_001	6 Month Follow-Up 01 Aug 2024-Follow-up Reporting Period and Patient Status	
1548_AFR_001	Baseline-Medical History	
1561_KMD_001	ARIA Adverse Events-ARIA Adverse Events	
1561_KMD_001	Concomitant Medications-Concomitant Medications	
... 81 82 83 84 85 86 87 88 89 90 ...		
1239-LW-01		

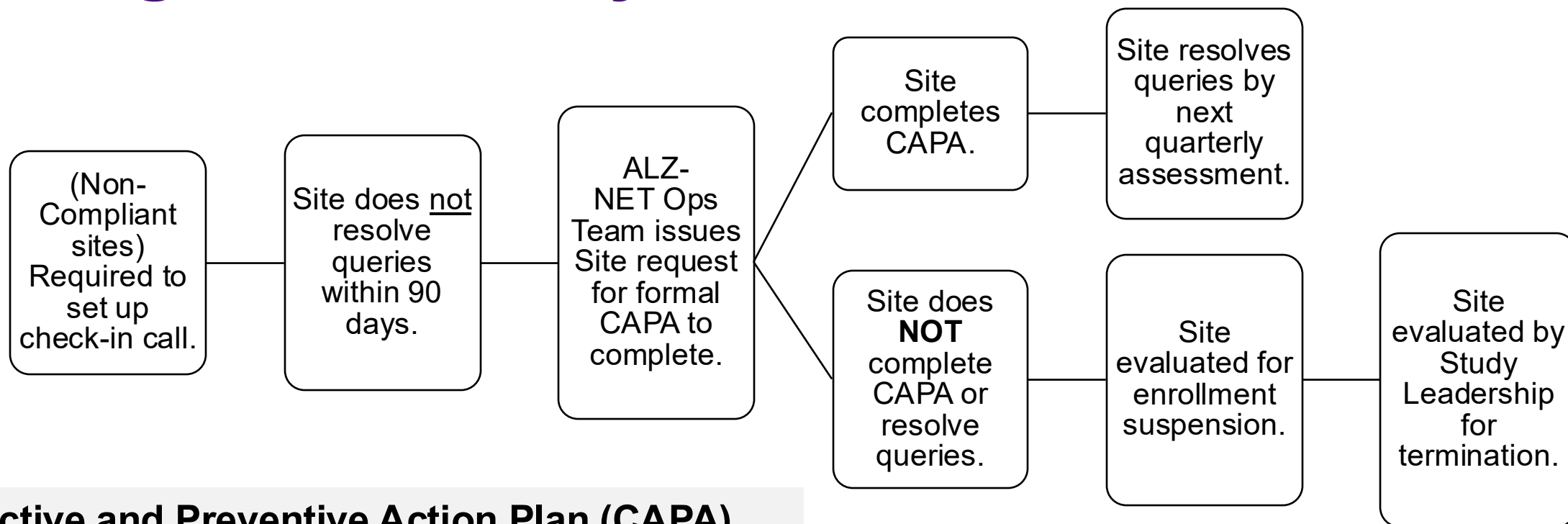
- Task summary located on right-hand side of homepage for each site/patient.
- Click on open queries or non-conformant data numbers to view list of corresponding outstanding data.
- Click on listed forms to be brought directly to them and address the issue.

Monthly Data Query Expectations



1. On the first of every month, the ALZ-NET Data Management (DM) Team sends each site a summary data query report.
2. Site assigns designated staff member(s) at site data query review responsibility.
3. Site reviews report and addresses all outstanding queries within **30 days** of receipt.
4. Site contacts DM Team with any questions or concerns at alznet-data@acr.org.
5. Outstanding queries that are not addressed by the next quarterly assessment report may impact a site's overall data compliance score.

ALZ-NET Data Quality Management Policy



Corrective and Preventive Action Plan (CAPA)

A systematic process used to identify and fix problems and to prevent them from happening again

Tips for Efficient Query Resolution

Organization & Tracking

Monitor Task Summary Tab in RAVE

Check the Task Summary tab in RAVE daily/weekly for your site to stay on top of outstanding data.

Use Monthly Query Report to catch any overdue data that may have been missed.

Reports are sent the 1st of each month, and can be used to filter/sort open queries and overdue forms to complete them in RAVE.

Use Filters to Sort Queries by Priority

In Medidata Rave/Monthly Query Report, sort queries by priority to address the most urgent ones first.

Use Color-Coding for Status Tracking

Differentiate between pending, in-progress, and resolved queries on your tracking sheet or dashboard for quick visual reference.

Tips for Efficient Query Resolution (continued)

Timeliness & Efficiency

Set up Internal Query Resolution Deadlines

Batch Query Responses Patient-by-Patient

Cross-check Data Before Data Entry

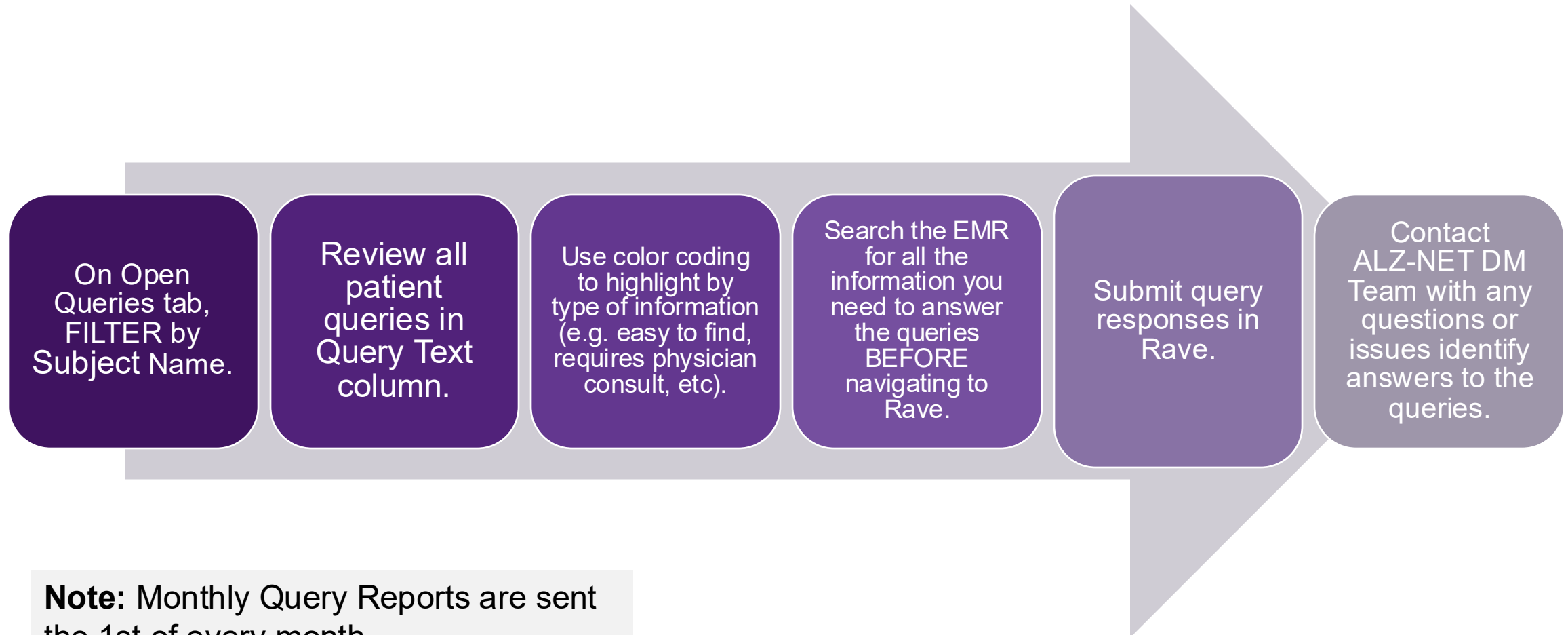
Communication & Collaboration

Hold Weekly Site Check-ins

Delegate Tasks Based on Expertise

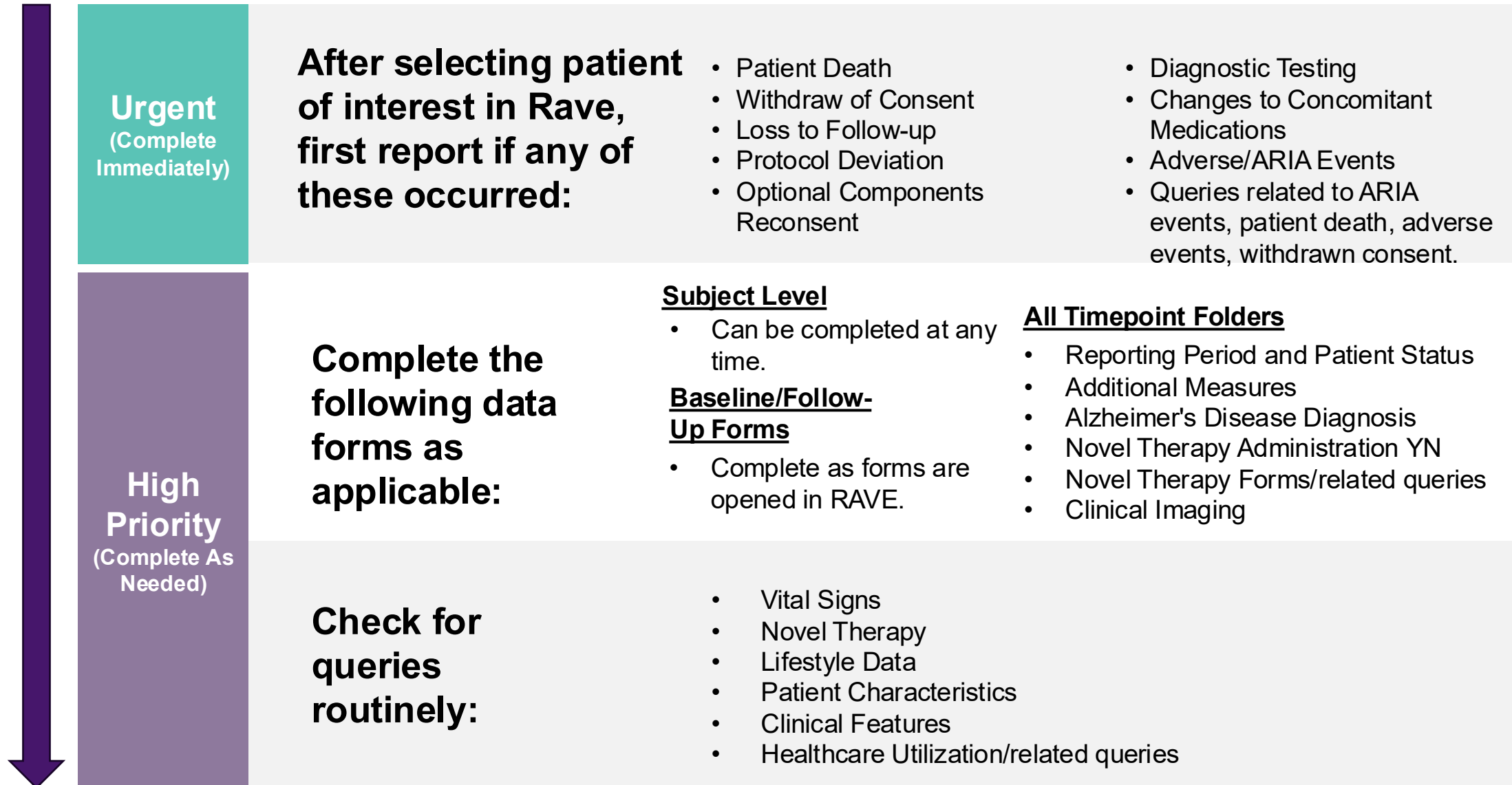
Request Help from the ALZ-NET Data Management Team

Using the Monthly Data Query Report



Note: Monthly Query Reports are sent the 1st of every month.

Data Timeliness and Form Resolution Priorities





ALZ-NET Operations Team

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