National Cancer Institute

CTMS ONCOLOGY | EXPERTS

Clinical Trials Monitoring Service
A SERVICE OF THE NATIONAL CANCER INSTITUTE

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Medidata Rave and IWRS/OPEN

Early Drug Development Meeting
April 21, 2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Agenda

- ❑ Registration
- ❑ Slot Reservations
- ❑ Cohort Management
- ❑ Medidata Rave
- ❑ Data Submission Guidelines
- ❑ Technical Support

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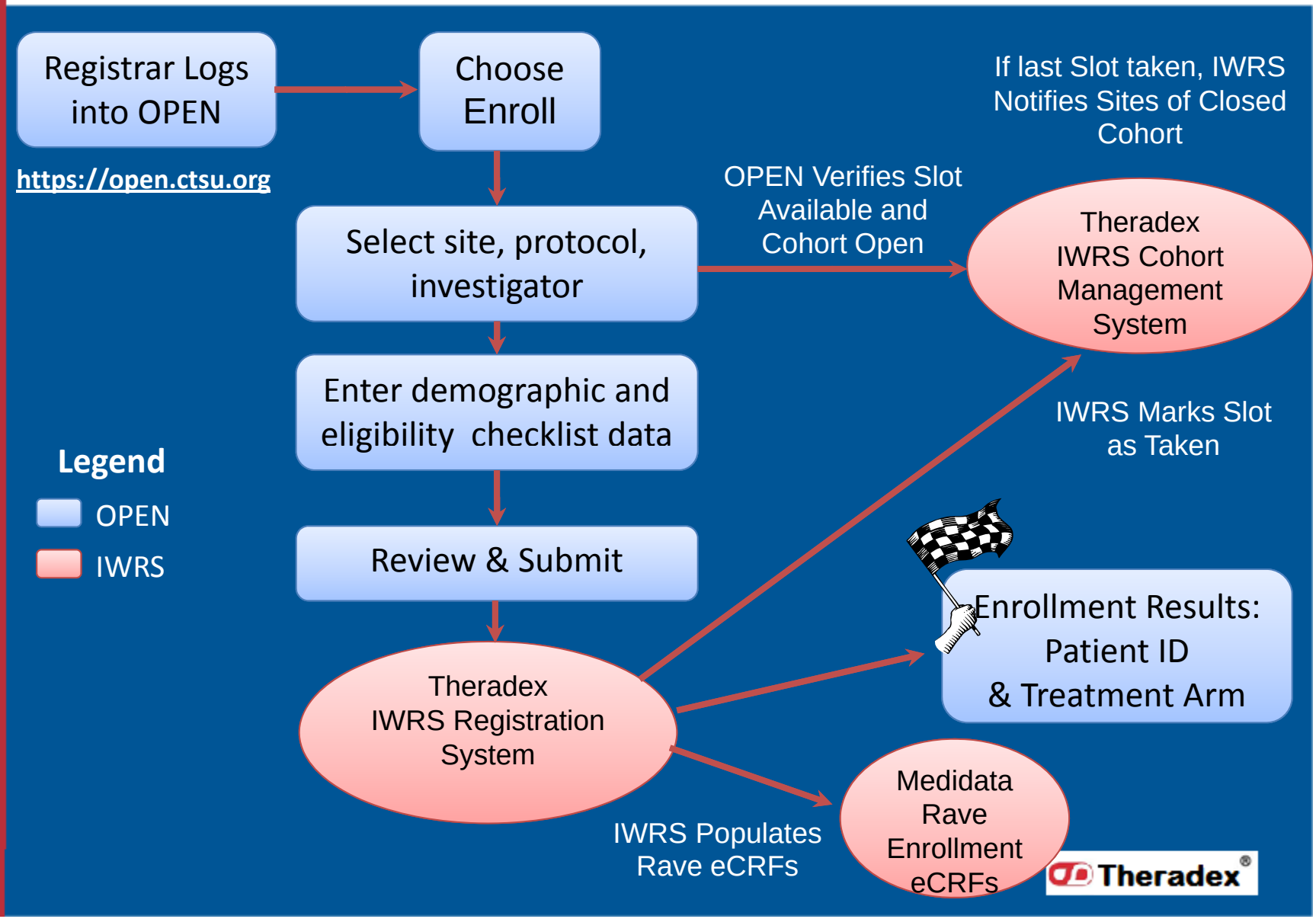
Example Registration Flow



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Example Theradex IWRS Slot Reservation Flow

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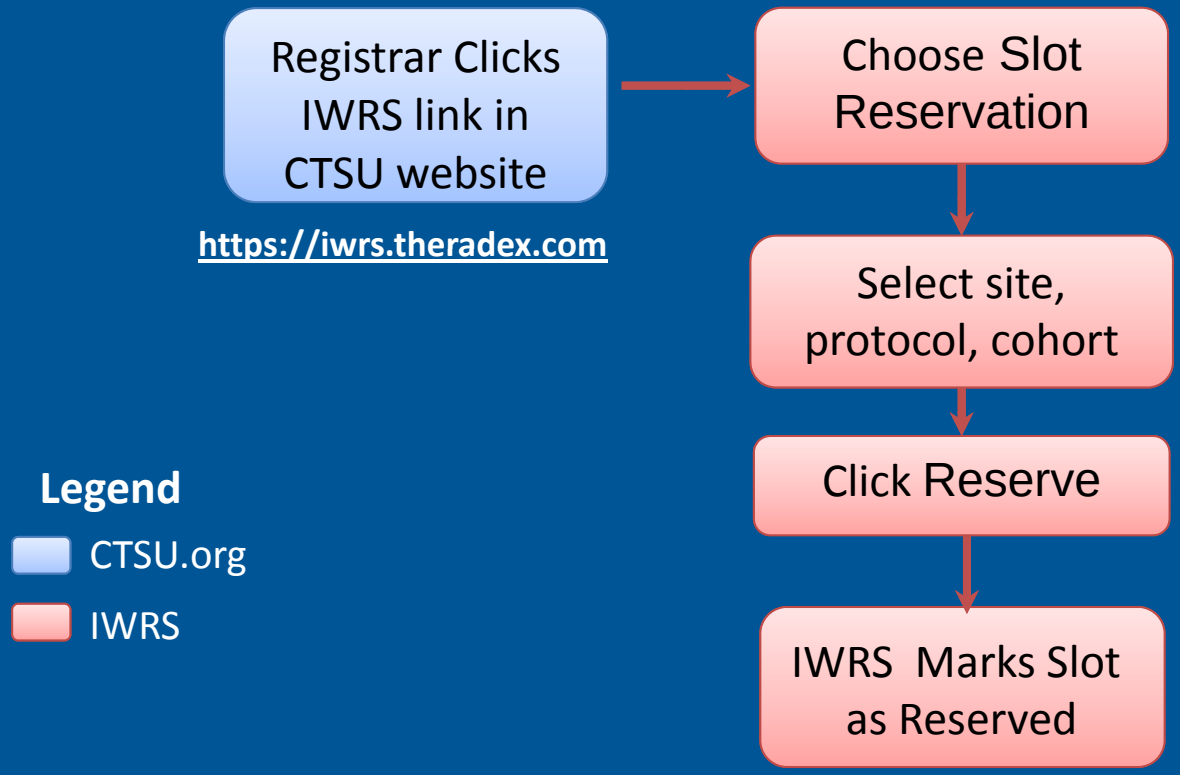

Legend

- CTSU.org
- IWRS

Optional Features:

- Slot Reservation Approvals
- Reminders of Unused Reservations

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Example Theradex IWRS Cohort Management Flow

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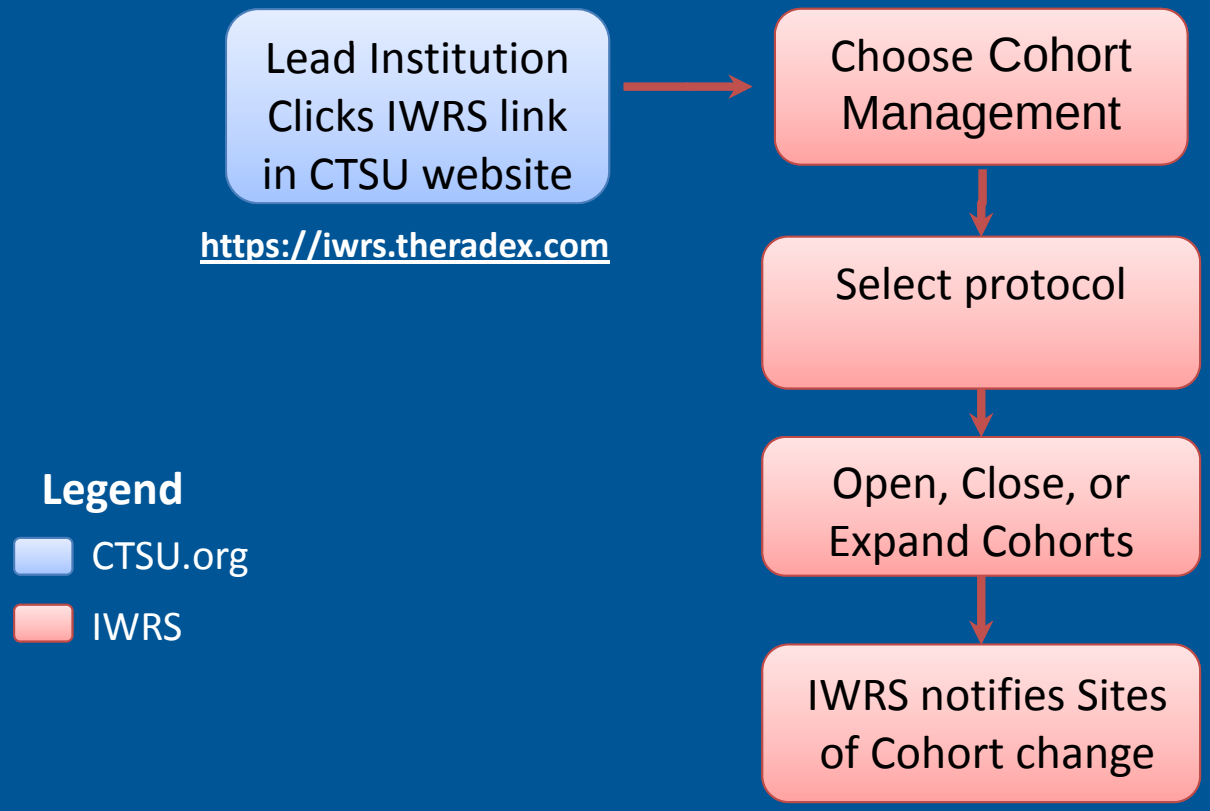

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Quick and Easy Cohort Management

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Open and Close Cohorts

Cohort	Accrual Limit	Slots Available	Active	Action
Cohort 1	5	2	☑	✓ ✗
Cohort 2	4	2	☐	
Cohort 3	6	3	☑	
Cohort 4	3	1	☑	

Instant Email Notifications to Sites

Reserve Slots

Cohort	Accrual Limit	Slots Available	Active	Action
Cohort 1	5	2	☑	Reserve
Cohort 2	4	2	☐	
Cohort 3	6	3	☑	Reserve
Cohort 4	3	1	☑	Reserve

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Medidata Rave

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- Web based EDC (electronic data collection) to be used in all future NCI studies
- All ET-CTN studies will use the same standard Theradex eCRFs resulting in expedited study set-up following approval
- Built-in, Real-time Edit Checks will minimize queries and after-the-fact data cleaning
- Queries entered by CTMS monitors and auditors can be resolved within Rave by the site staff

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Medidata Rave Screenshot

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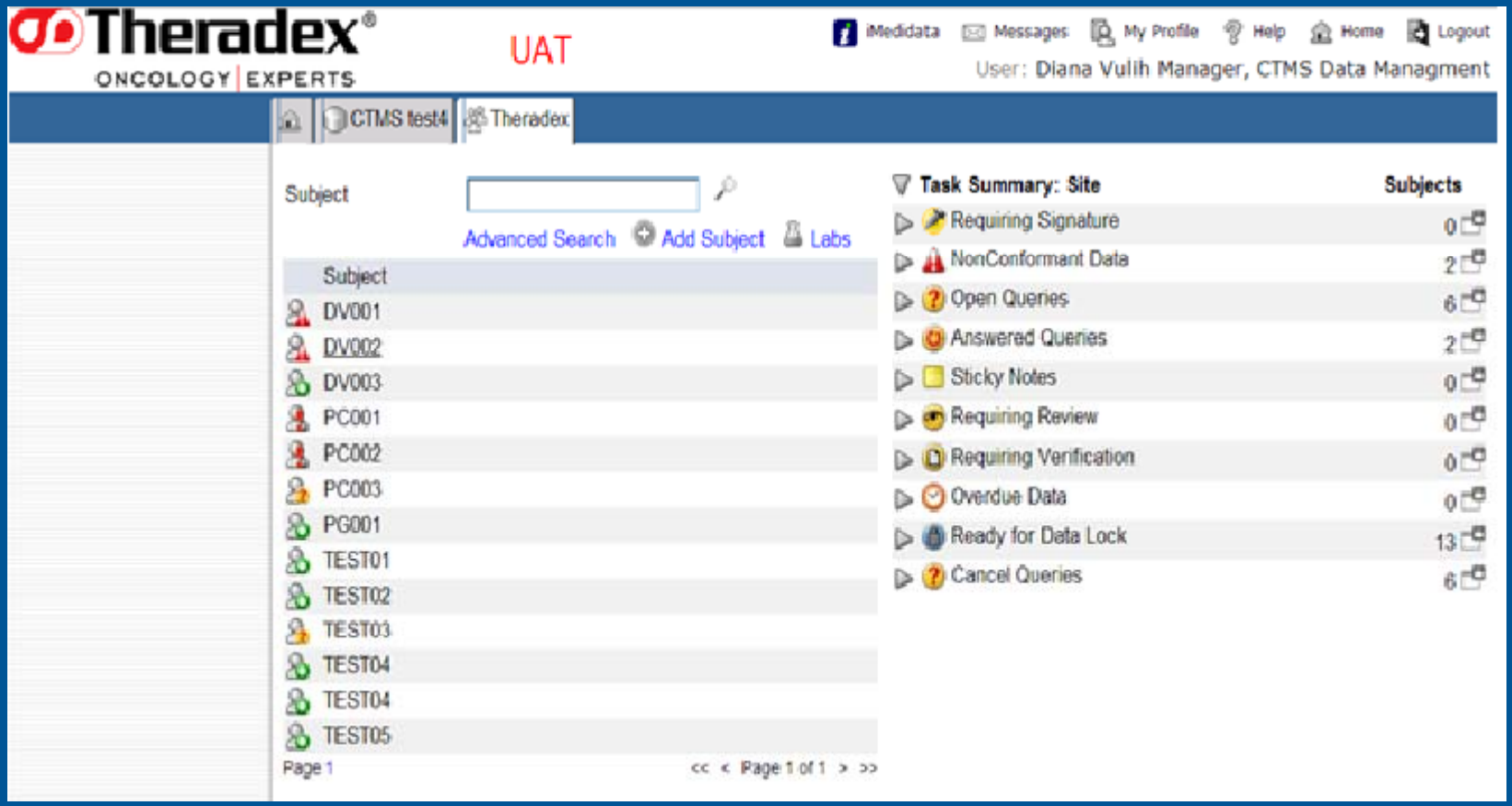

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Data Submission Guidelines

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- All data is to be submitted within 2 weeks from when it becomes available to the site
- Queries should be answered within 2 weeks of being issued
- Task Summary makes it easy to track what tasks are pending (e.g. non-conformant data, open queries, overdue data, etc.) for a study or a patient.

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End of Study Report

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- Theradex will create End of Study Report within 60 days of last patient completing
- End of Study Report will be used for Statistical analysis, and have a sub-report with a subset of data.
- Summary Reports for FDAAA Applicable Clinical Trials (ACT)

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Technical Support

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- Theradex provides Rave User Guide
- Theradex will provide support for IWRS and Rave
- CTSU will provide support for RSS and OPEN

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