Data Collection & Management

Investigator Meeting
12th September 2017 - Sheffield

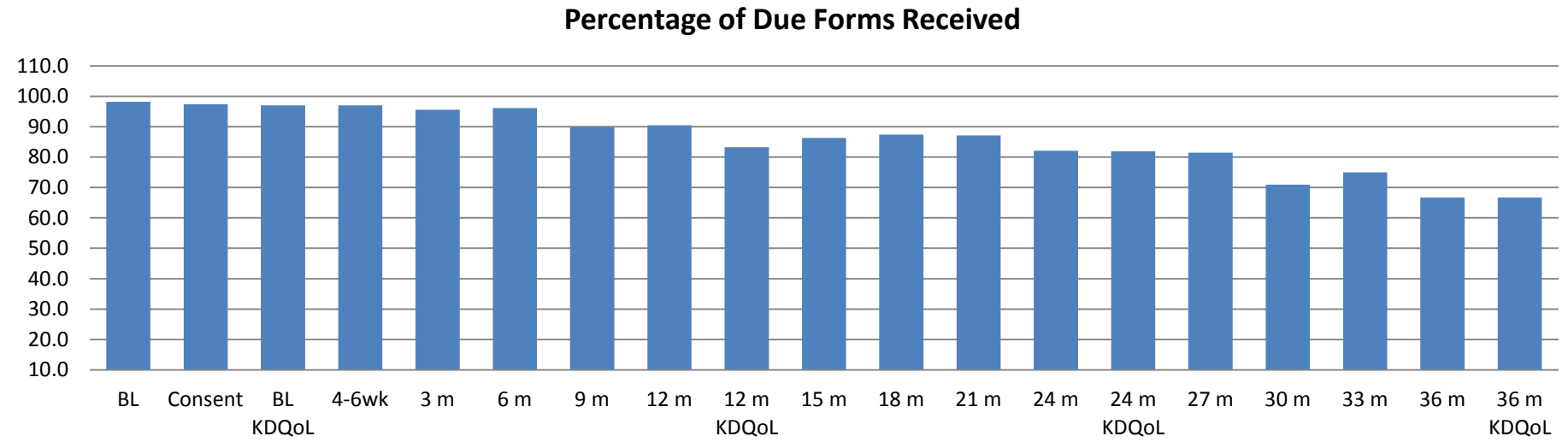
Jamie Godsall
Data Manager, BCTU

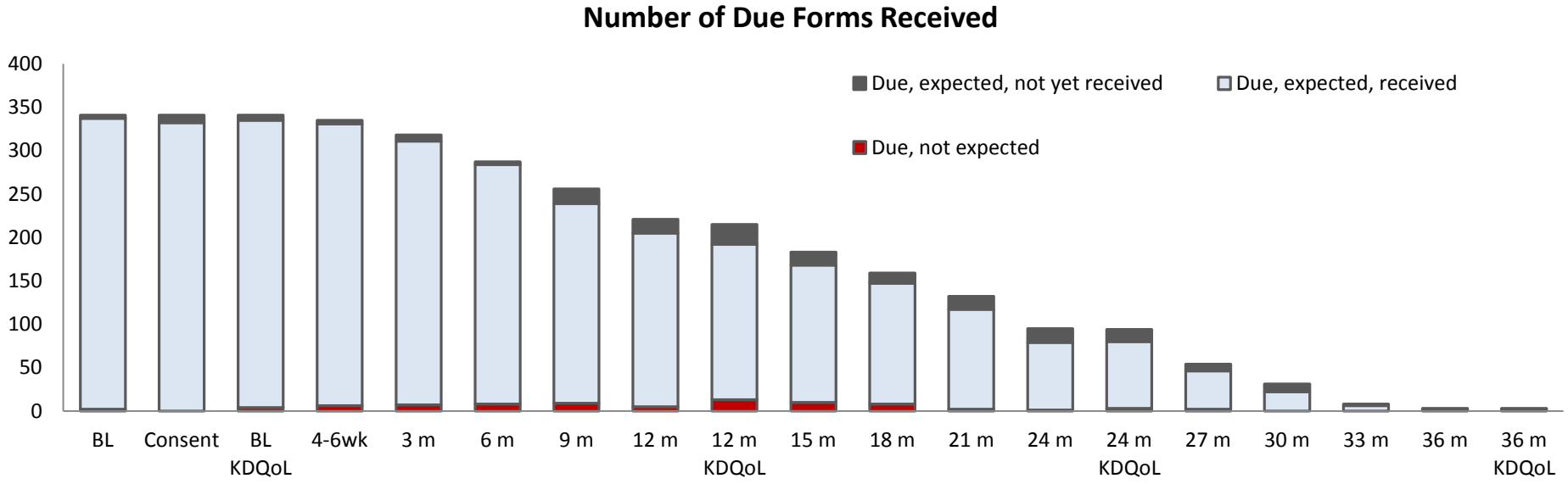
UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit | Hull and East Yorkshire Hospitals NHS Trust | NHS

CRF return rates

Form	Time point	Forms expected	Forms received	Percentage received
Baseline	BL	339	335	98.8
Consent	Consent	341	332	97.4
KDQOLSF	BL KDQoL	337	331	98.2
Phone call	4-6wk	329	325	98.8
Follow Up	3 m	311	304	97.7
Follow Up	6 m	279	276	98.9
Follow Up	9 m	247	230	93.1
Follow Up	12 m	216	200	92.6
KDQOLSF	12 m KDQoL	202	179	88.6
Follow Up	15 m	173	158	91.3
Follow Up	18 m	151	139	92.1
Follow Up	21 m	130	115	88.5
Follow Up	24 m	94	78	83.0
KDQOLSF	24 m KDQoL	91	77	84.6
Follow Up	27 m	52	44	84.6
Follow Up	30 m	31	22	71.0
Follow Up	33 m	8	6	75.0
Follow Up	36 m	3	2	66.7
KDQOLSF	36 m KDQoL	3	2	66.7
Totals		**3337**	**3155**	**94.5**

CRF return rates





ICFs

Participant consent forms should either be faxed or emailed to our NHS email address. Please send these as soon as possible after randomisation.

@NHS stop.ace@nhs.net

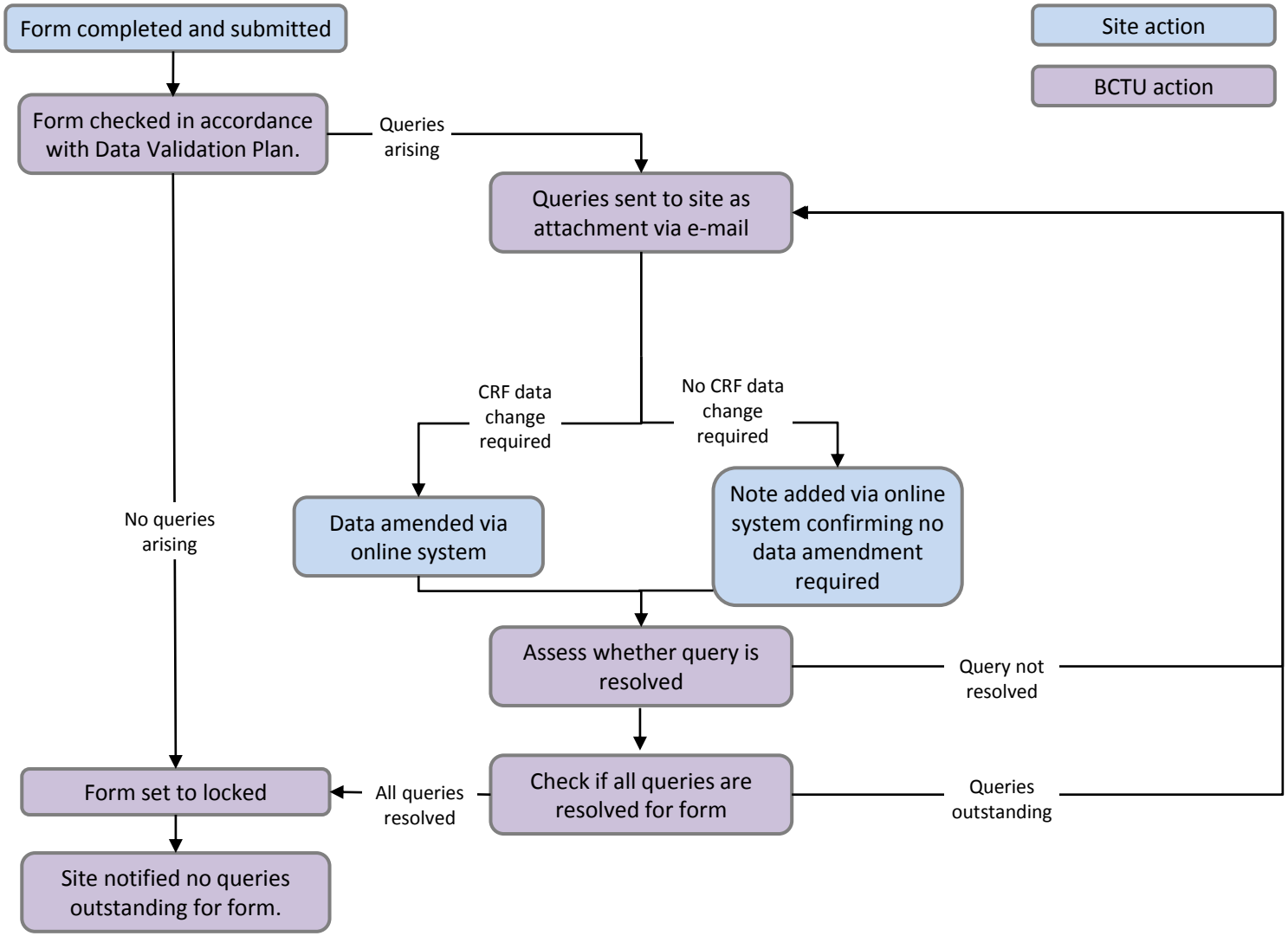
0121 415 9135

Online system

- To access the STOP-ACEi online system you must have a username and have set-up a password
- To add new staff to the trial we require:

- Data **must** be entered into online system from the source data
- You should have corresponding source data which must tally with everything submitted on the eCRF

Query Process

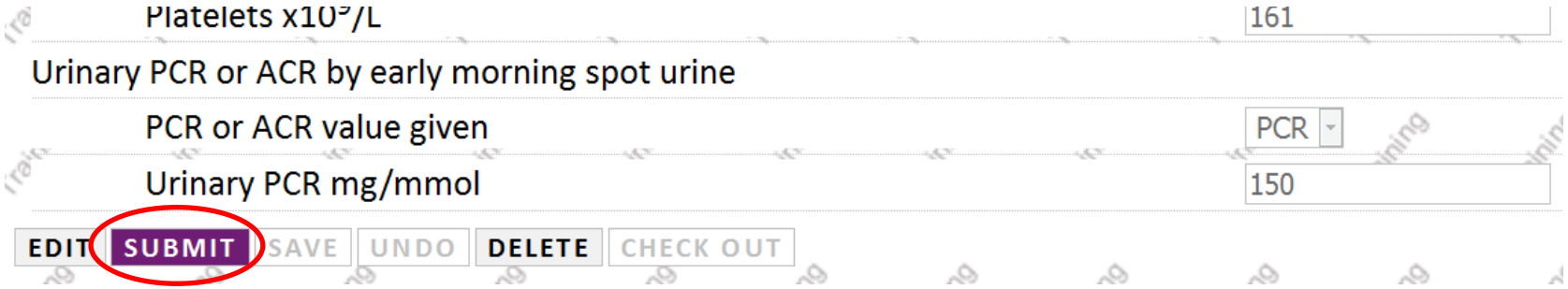


Query Process

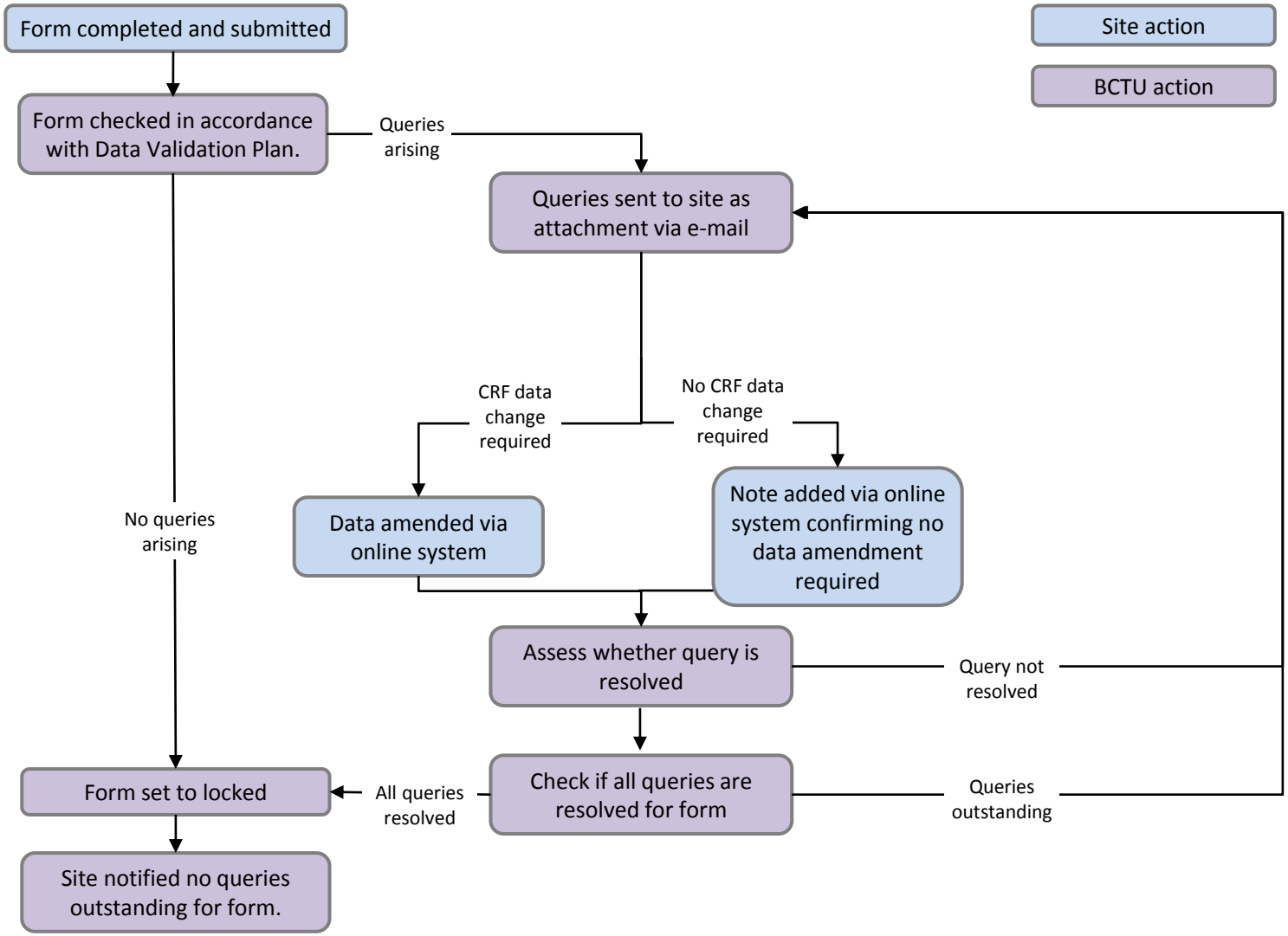
Form completed and submitted

Please remember to submit eCRFs once completed

This lets me know that you have finished data entry and the form can be checked



Query Process



Query Process

Form checked in accordance with Data Validation Plan.

Lab Assessments

If a result is missing please leave the field blank

Field should be left blank:

and note added explaining

Compliance

If a patient has withdrawn from trial treatment please report non-compliance on every subsequent eCRF where they remain non-compliant.

Annual visits (month 12, 24 and 36)

There have been a number of six-minute walk tests and questionnaires missed at the annual follow-ups. This data is important to the trial and should be obtained if possible.

Query Process

Form checked in accordance with Data Validation Plan.

Please complete all drop down boxes

BASIC ASSESSMENTS | CKD AETIOLOGY | CARDIOVASCULAR EVENTS | HEART FAILURE | MED HISTORY | ADMIN - VIEW AUDIT | ADMIN - VIEW CHANGES

Please indicate all conditions the patient has a known history or current diagnosis of.
Heart failure, stroke and MI should be recorded in the previous sections

Please indicate all conditions the patient has a known history or current diagnosis of.

Other Cardiovascular Disease	Yes
Diabetes	Yes
Malignancy	
Gastrointestinal	
Musculoskeletal or connective tissue disorders	
Infection	
Pulmonary Disease	
Other	Yes

Form Status: Data Entry In Progress

There are 6 queries for this form

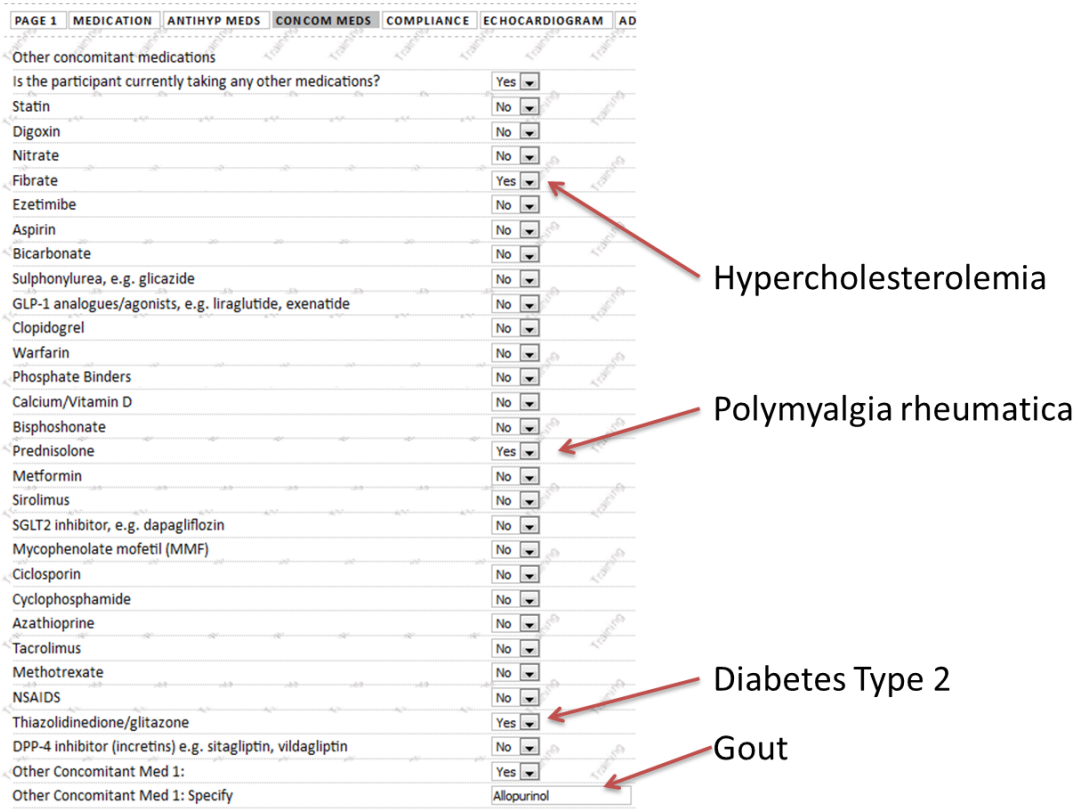
- "Med History : Malignancy" has not been answered
- "Med History : Gastrointestinal" has not been answered
- "Med History : Musculoskeletal or connective tissue disorders" has not been answered
- "Med History : Infection" has not been answered
- "Med History : Pulmonary Disease" has not been answered
- Baseline Medical History Form "Page 1 : Condition category" has not been answered

The system will query missing data

Query Process

Form checked in accordance with Data Validation Plan.

A lot of queries are around medications with no corresponding medical condition. Please ensure that the patient's full medical history is included at baseline and new conditions are added after follow-up visits.

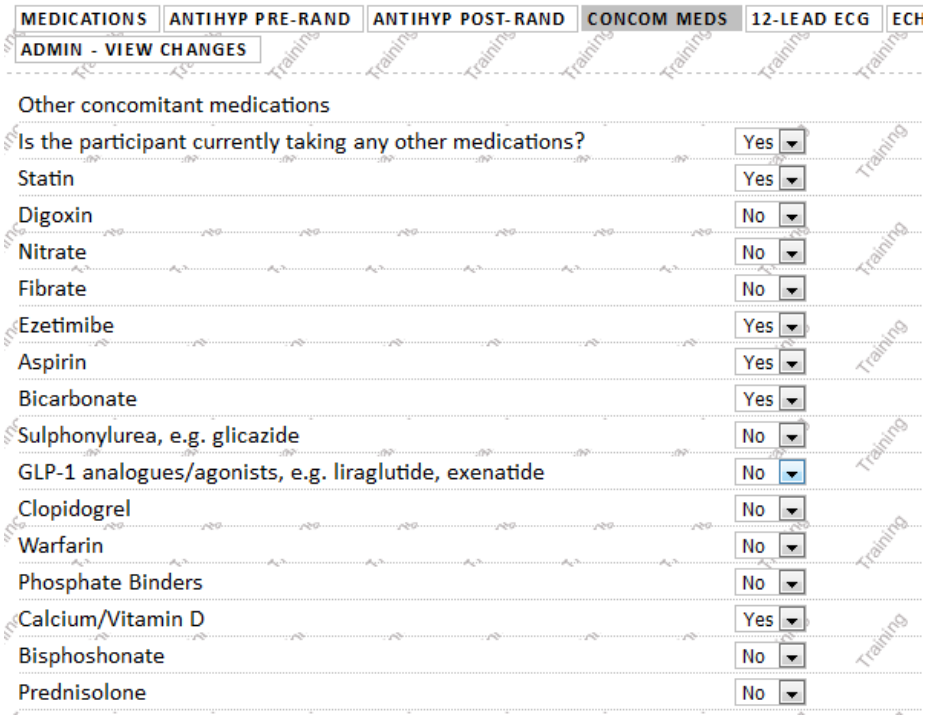


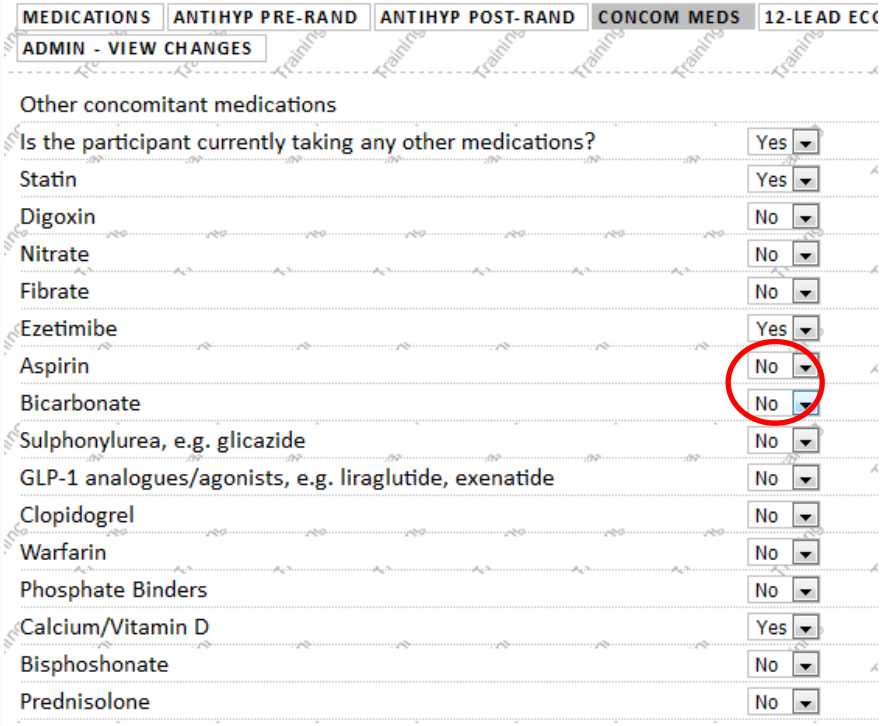
Query Process

Form checked in accordance with Data Validation Plan.

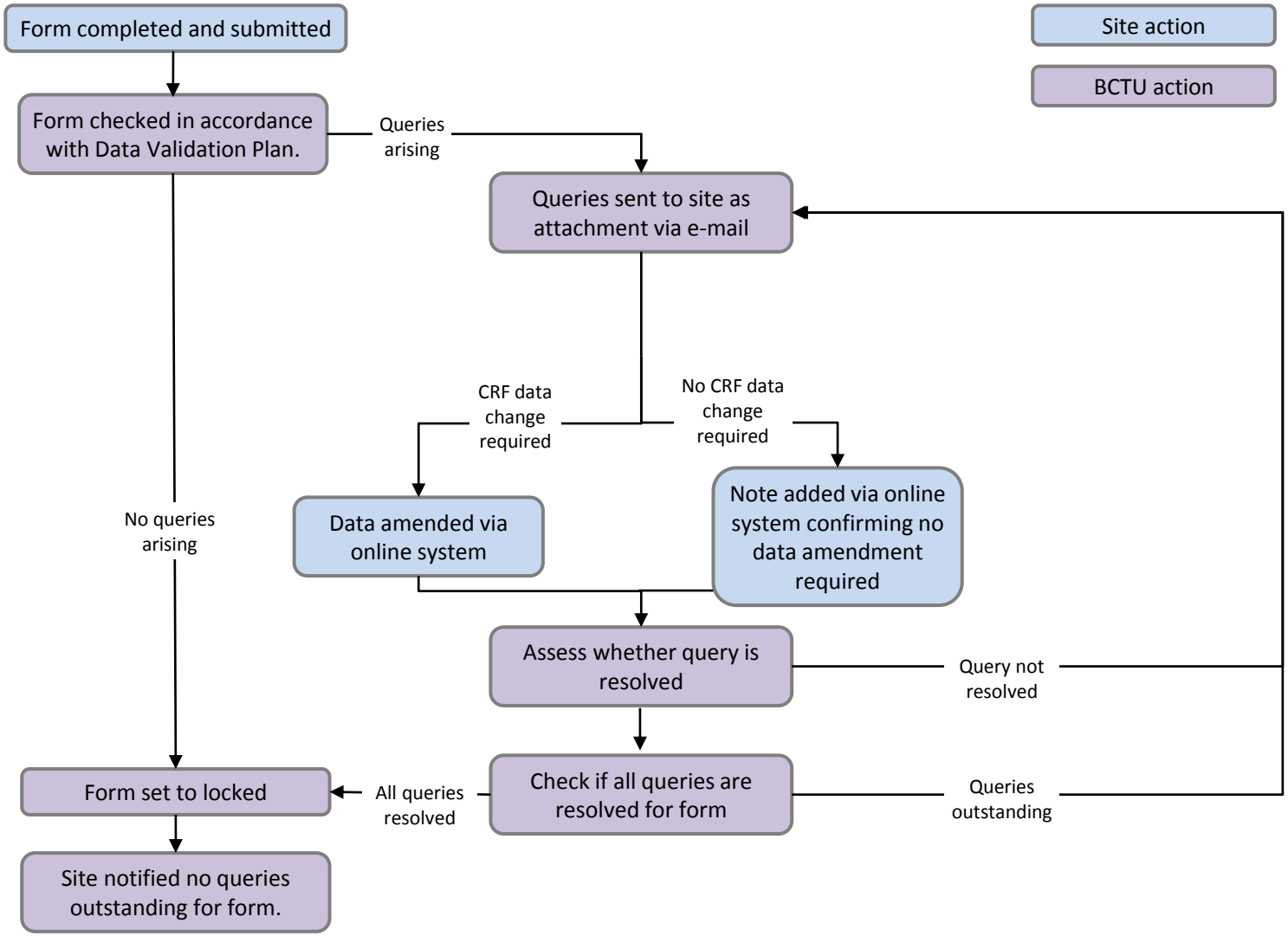
Differences between trial visits

Queries are often raised about differences between trial visits with no explanation (e.g. no note added, no new medical condition, no SAE or adverse event).





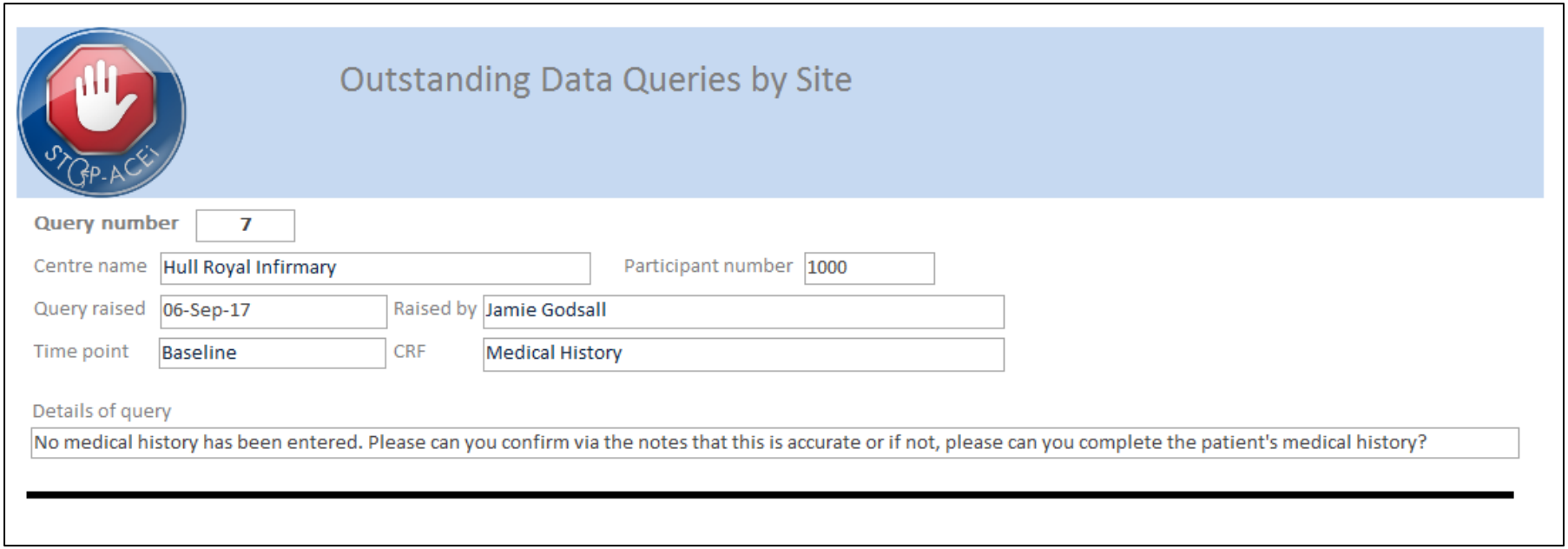
Query Process



Query Process

Queries sent to site as attachment via e-mail

Instead of a list of queries via email, queries will now be sent in a standard format as a pdf email attachment :



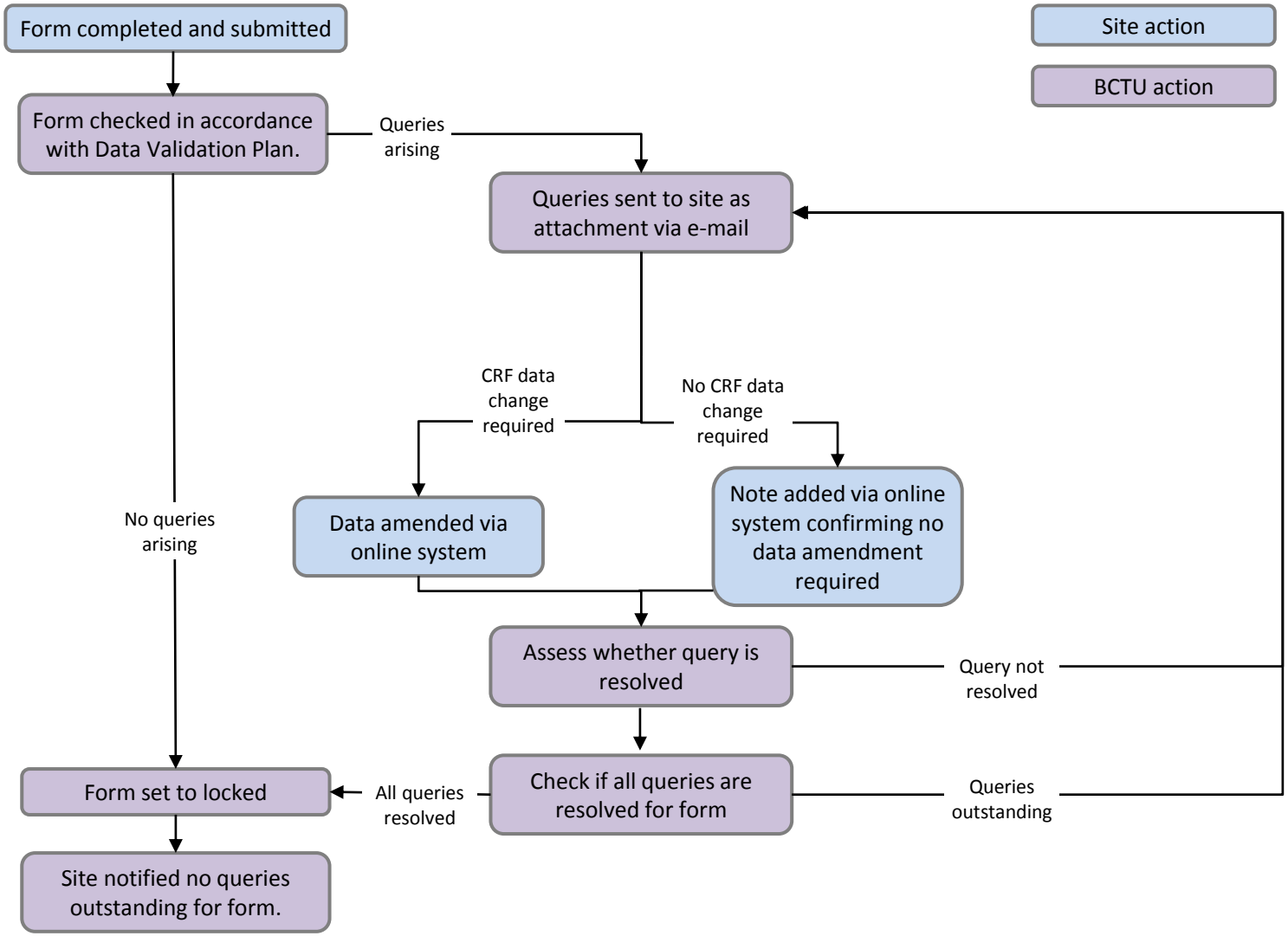
Outstanding Data Queries by Site

Query number	7		
Centre name	Hull Royal Infirmary	Participant number	1000
Query raised	06-Sep-17	Raised by	Jamie Godsall
Time point	Baseline	CRF	Medical History

Details of query

No medical history has been entered. Please can you confirm via the notes that this is accurate or if not, please can you complete the patient's medical history?

Query Process



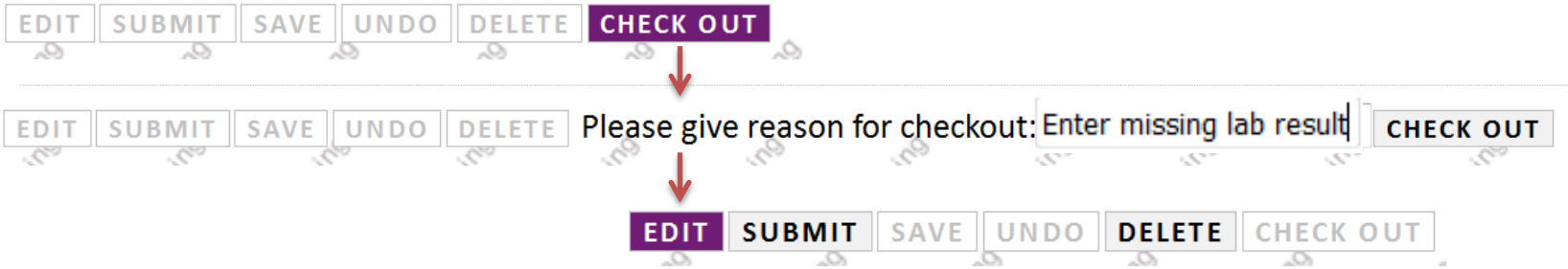
Query Process

Data amended via online system

If data needs amending sites must update the eCRF

BCTU staff are now locked out from making changes to the data

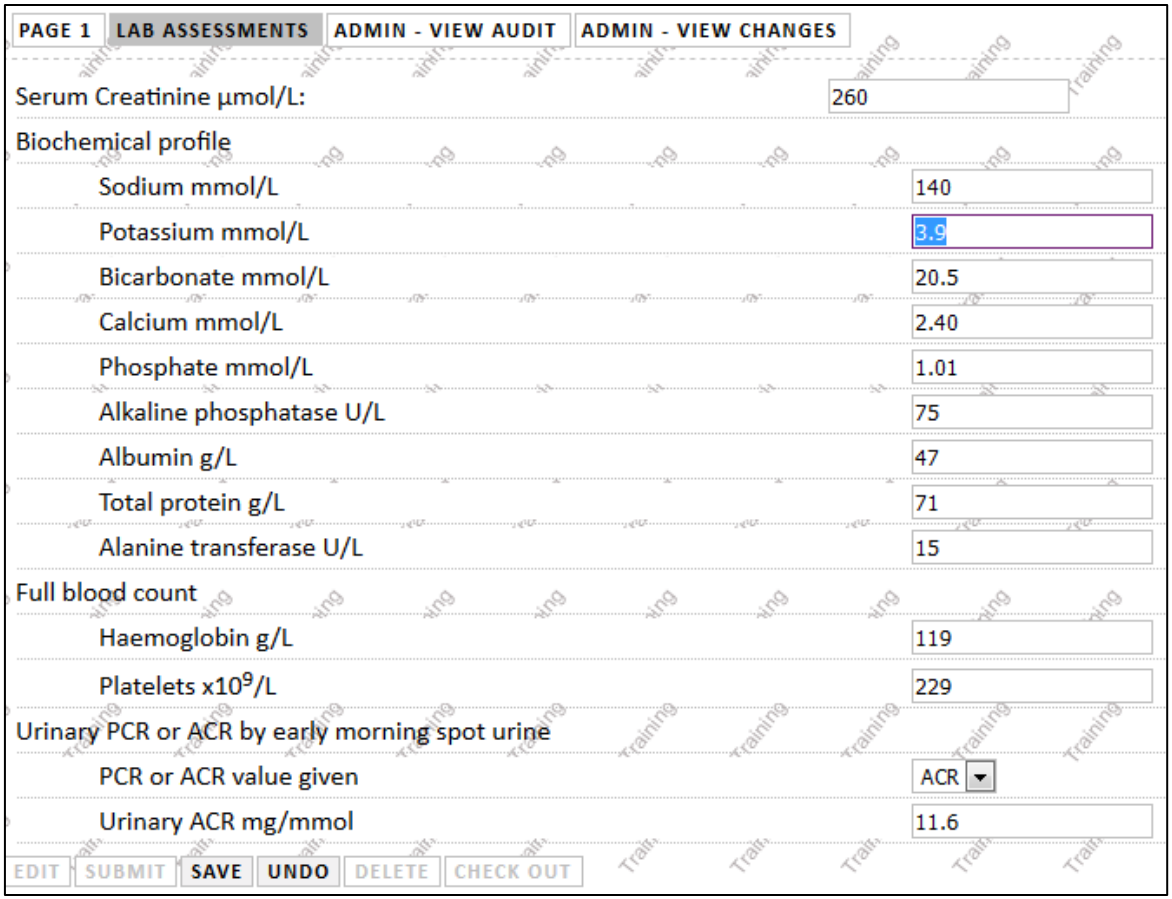
You can check forms out to edit after they have been submitted (as long as I haven't locked them)



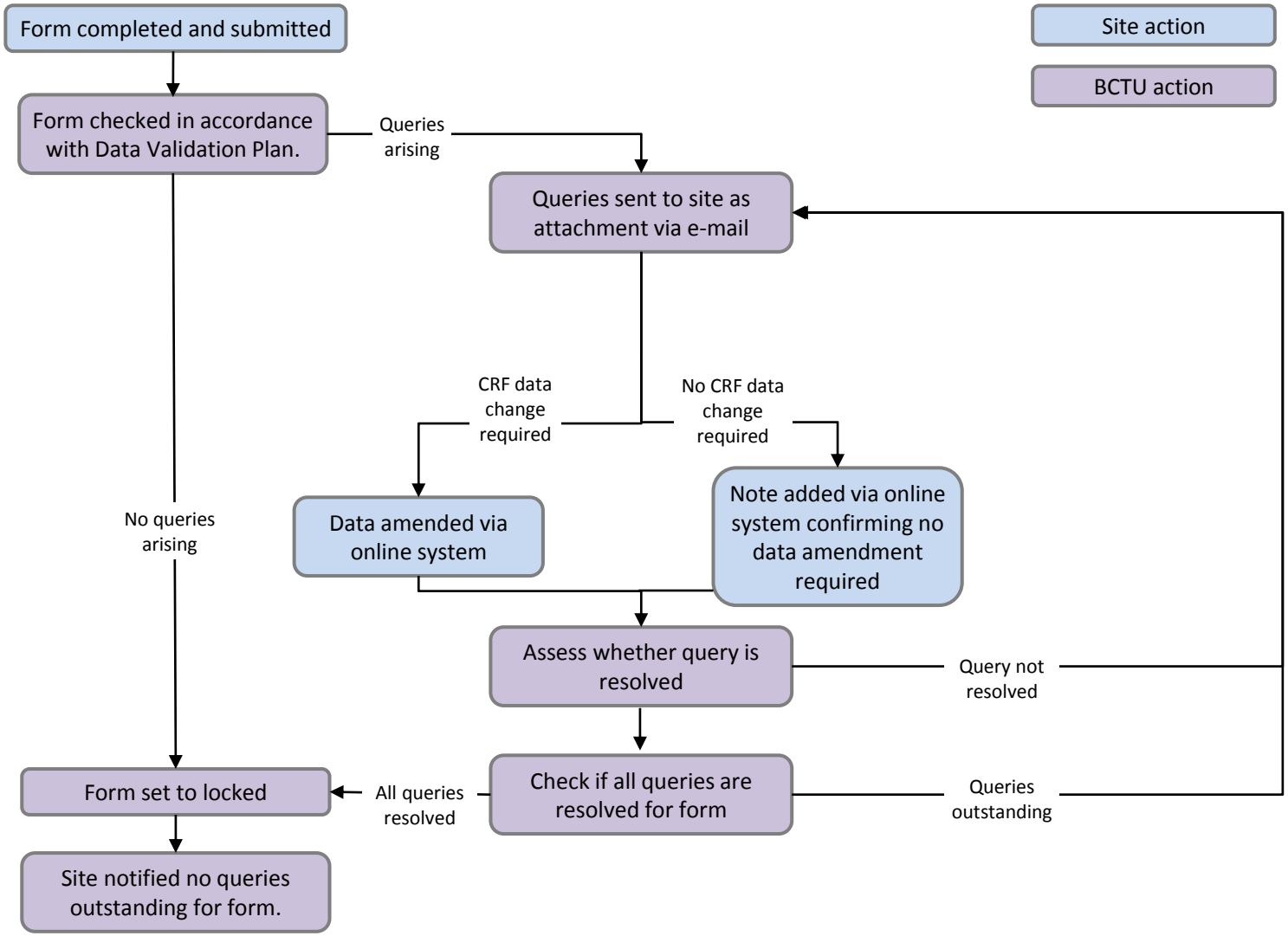
Query Process

Data amended via online system

Site updates eCRF, then saves **and submits** the form again



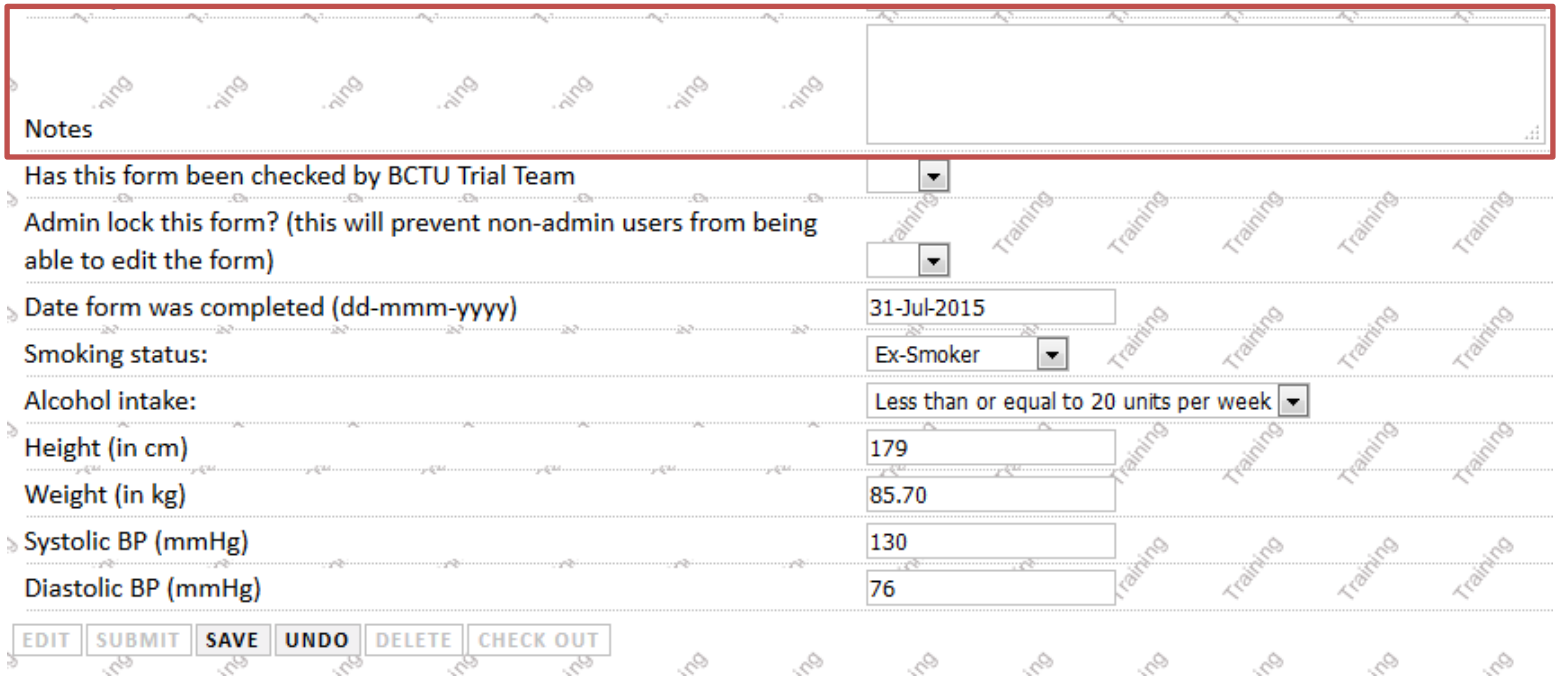
Query Process



Query Process

Note added via online system confirming no data amendment required

Note boxes can be found on each part of the eCRF:

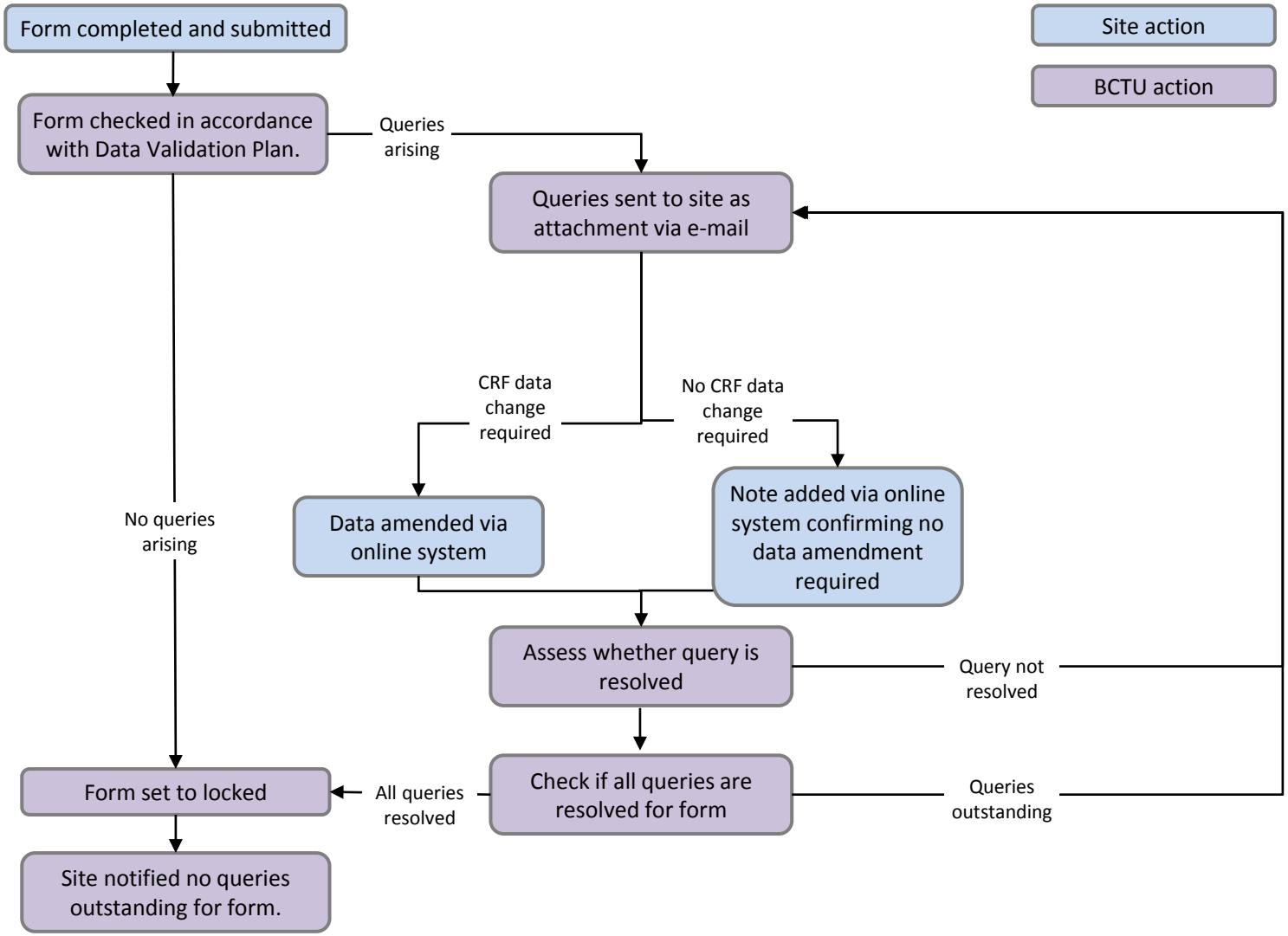


Query Process

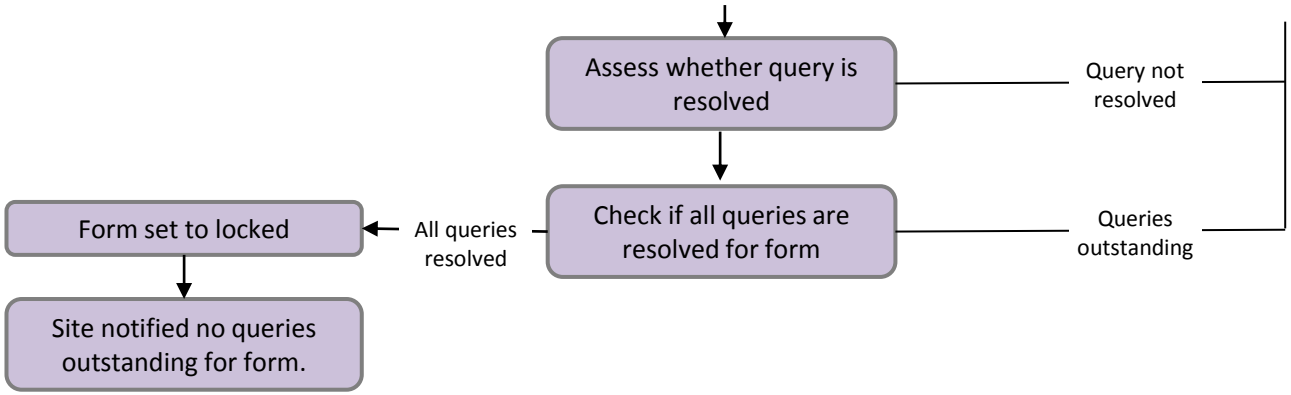
Note added via online system confirming no data amendment required

Notes	Query 7: No bicarbonate or protein result available from this visit
Notes	Query 15: Confirm Doxazosin dose has increased to 8mg daily and patient has stopped taking Atenolol
Notes	Query 24: Confirm patient has stopped taking Aspirin and Tramdol (as of 06Sep17) and started Allopurinol (gout - already added to Adverse Events)
Notes	Query 33: Patient had stopped taking Amoxicillin by this trial visit
Notes	Query 42: Unsure if patient was seen in primary care so box left blank

Query Process

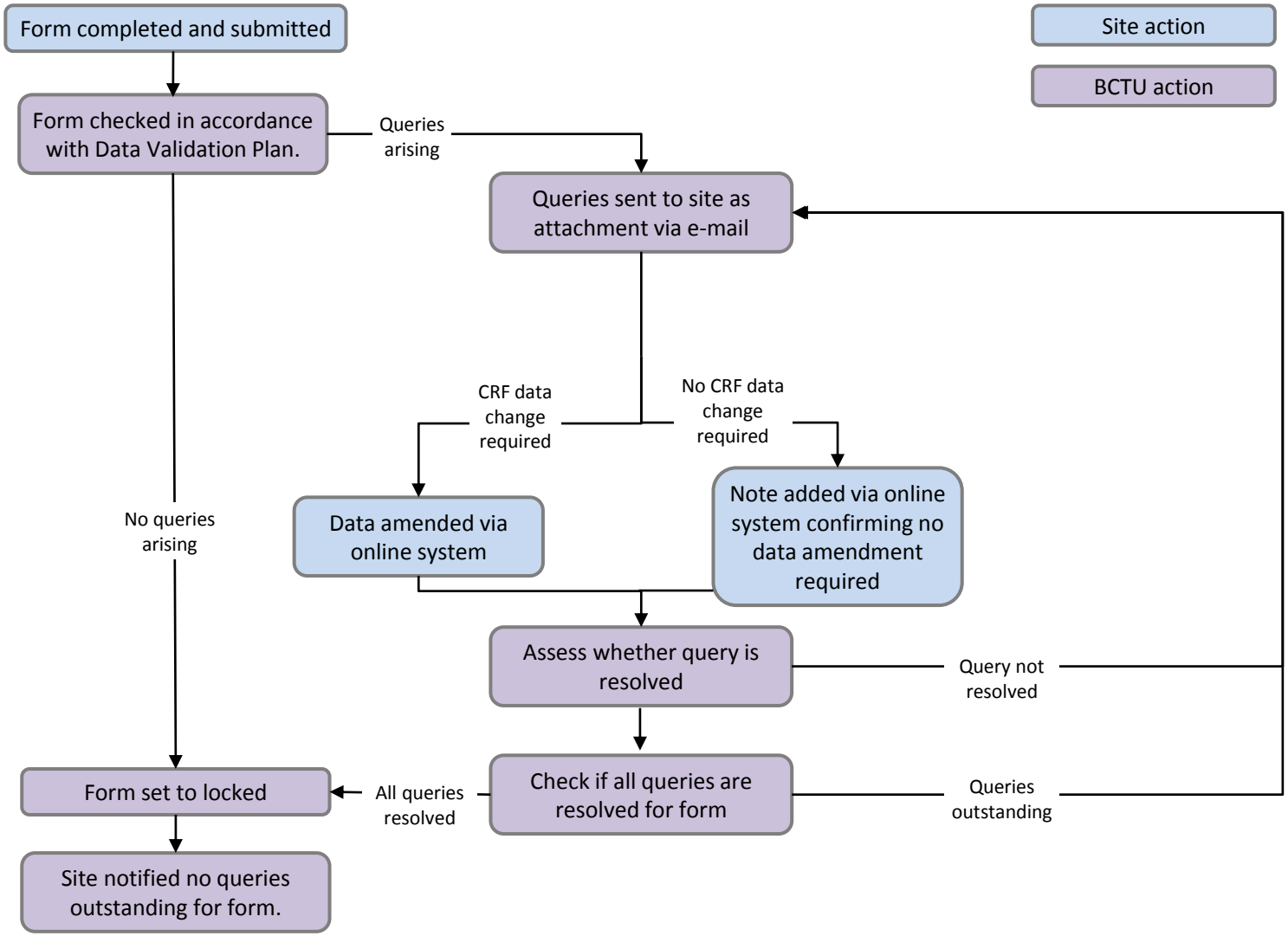


Query Process

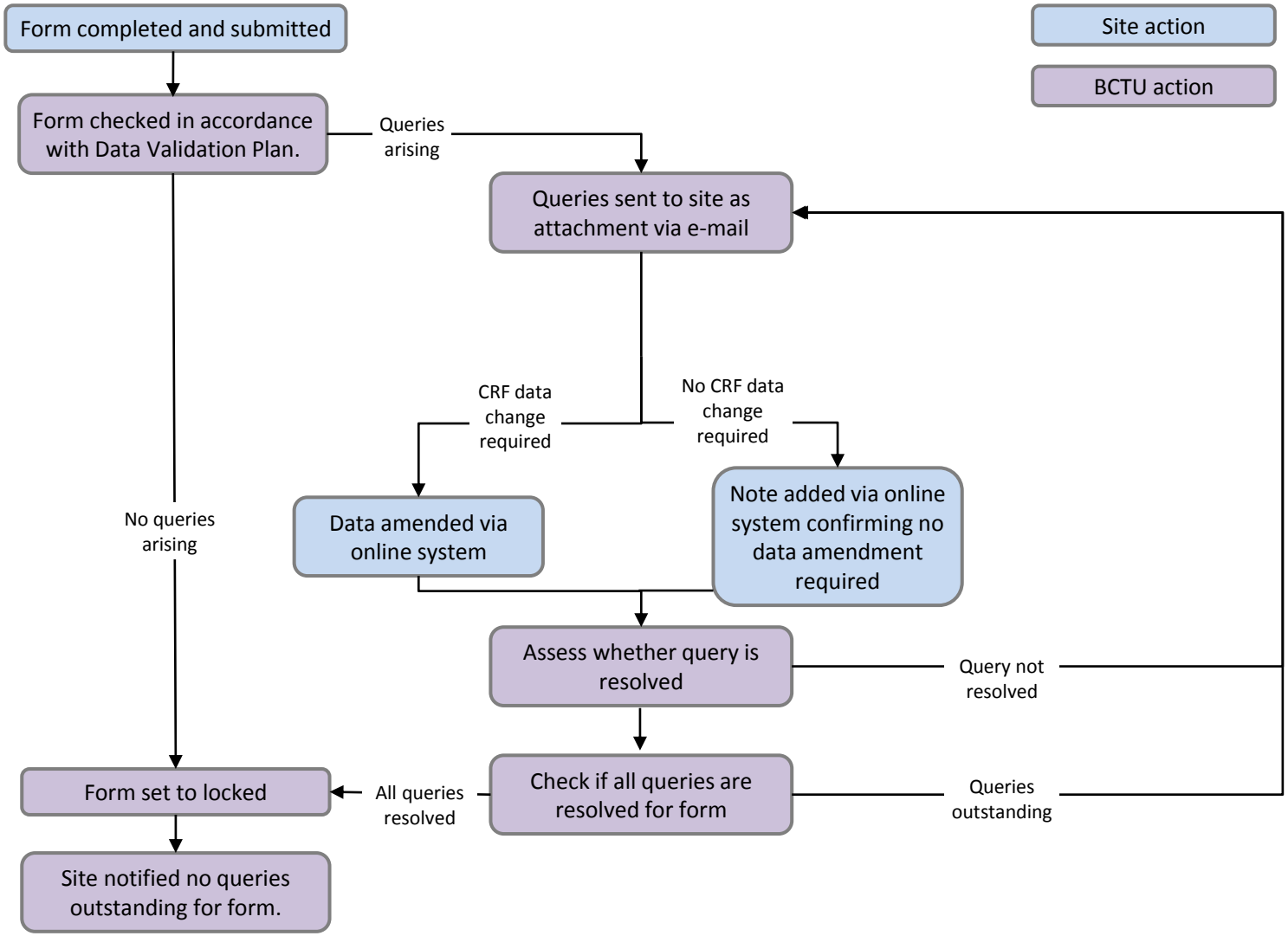


- BCTU will check the form once it has been updated
- If queries are outstanding or a query is not resolved completely a new query will be raised
- Once all queries have been completed the eCRF will be locked. However, if you need to make changes the form will be unlocked again.
- BCTU will send an email notifying sites once queries have been resolved

Query Process



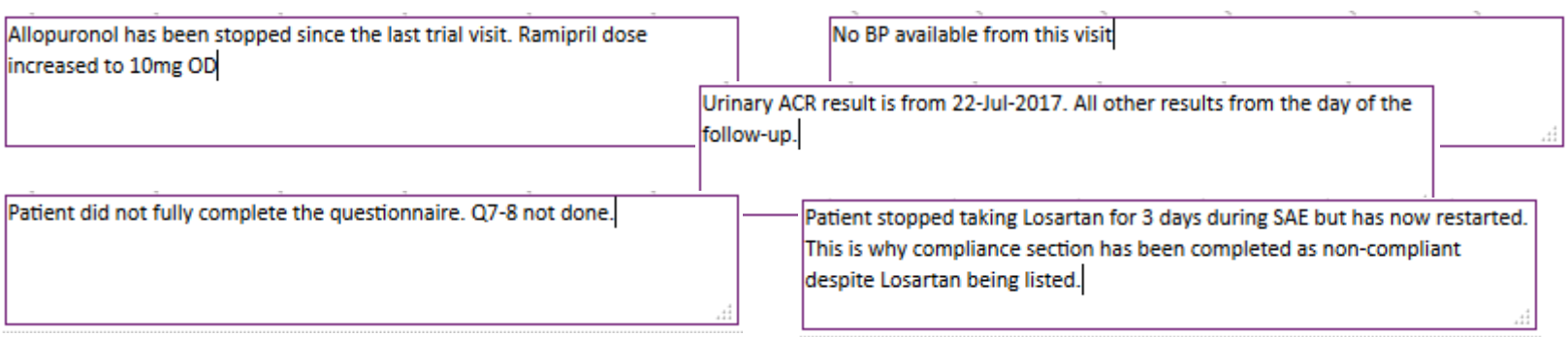
Query Process



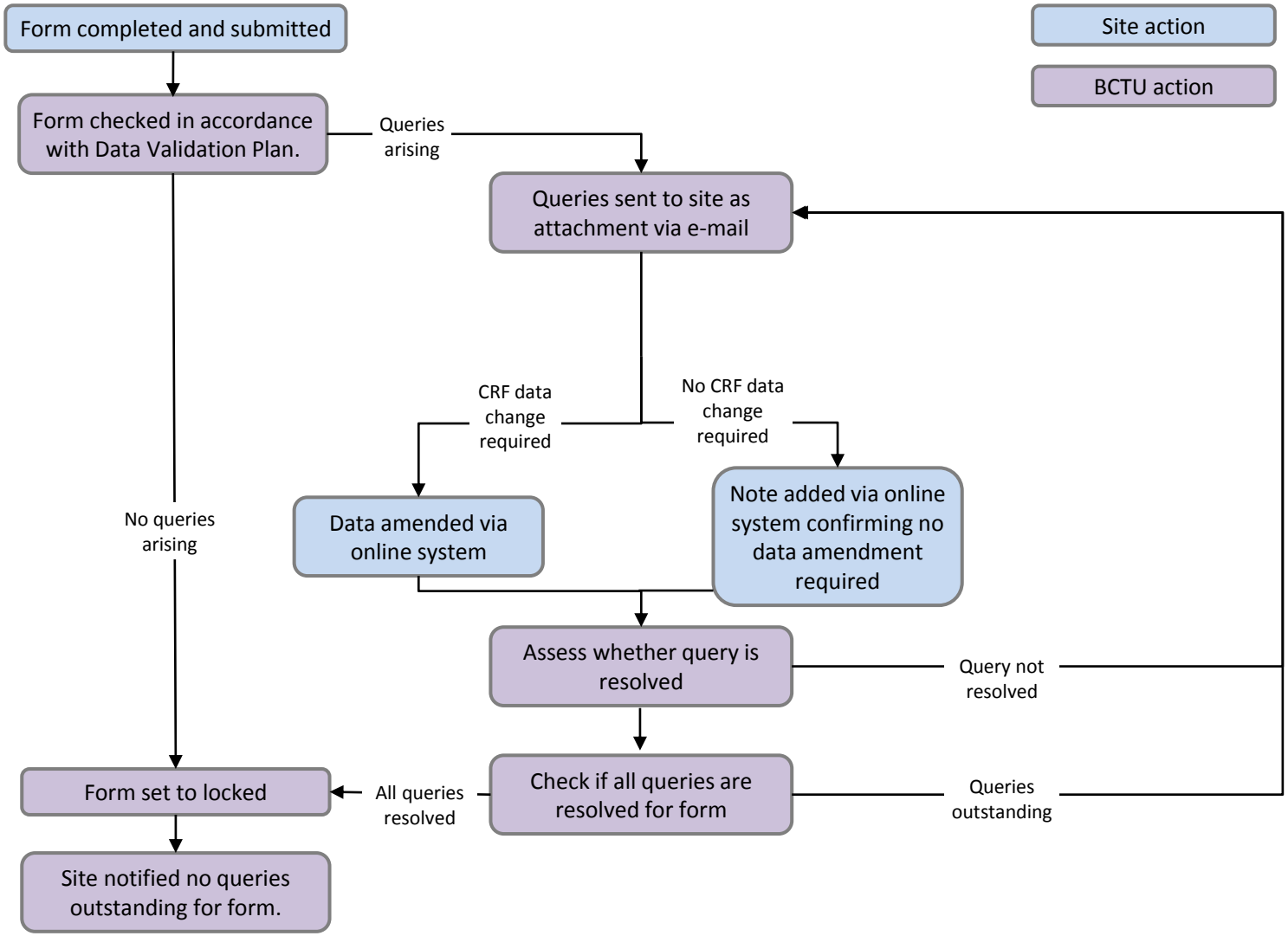
Query Process

Add notes to minimise queries and to let us know additional information

- Medication changes
  - Medication stopped or started
  - Dose or frequency changed
  - Why a patient has started a medication if no adverse event listed
- Missing lab results
- Incomplete data
- Visit done outside window
- Lab results are from different dates



Questions on the query process?



www.birmingham.ac.uk/STOPACEi

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Recruitment

Last updated 21 Aug 2017

STOP-ACEi is open to recruitment. We aim to recruit 410 patients from centres acros

Overview

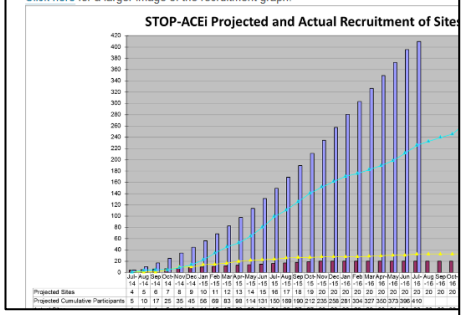
Date first participant randomised

Total recruitment to date

Total number of centres with full approval

STOP-ACEi Patient Recruitment

Click here for a larger image of the recruitment graph.



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Trial Documentation

These documents are for use by collaborators involved in the STOP-ACEi trial. They are the property of the University of Birmingham and Hull and East Yorkshire Hospitals NHS Trust and do not constitute any form of advice to participants.

Please see links below to download STOP-ACEi documentation.

In 'For Investigators'

- For Investigators
- Trial Documentation
- Recruitment

STOP-ACEi Protocol and REC-approved study documents

STOP-ACEi Protocol

STOP-ACEi Protocol, V3.0, 14th May 2014

MRC START in STOP-ACEi Protocol, V1.0, 10th December 2014

STOP-ACEi PIS, GP Letters & Consent Form

STOP-ACEi Participant Information Sheet, V3.0 Standard, 10th December 20

STOP-ACEi Participant Consent Form, V3.1, 24th March 2015

STOP-ACEi GP Letter - Treatment Continuation, V2.0, 6th January 2014

STOP-ACEi GP Letter - Treatment Discontinuation, V2.0, 6th January 2014

STOP-ACEi Other REC-approved documentation

STOP-ACEi Letter to accompany PIS, V2.0 Standard, 10th December 2014

STOP-ACEi Participant Advice Letter - Treatment Continuation, V1.0, 1st No

STOP-ACEi Participant Advice Letter - Treatment Discontinuation, V1.0, 1st

STOP-ACEi Participant Diary, V1.0, 1st November 2013

STOP-ACEi Clinic Poster, V2.0, 6th January 2014

STOP-ACEi Advertising Text, V1.0, 1st November 2013

Version history

List of current documents and amendment log, last updated 14th August 201

STOP-ACEi CRFs and KDQOL-SF™ questionnaire

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STOP-ACEi

STOP-ACEi is a national multi-centre randomised controlled trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease.

In 'STOPACEi'

- Birmingham Clinical Trials Unit (BCTU)
- **STOPACEi**
- For Investigators
- For Trial Participants
- News and events
- Publications
- Contact us

Trial details

Full Title: Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease

Short Title: The STOP-ACEi Trial

Aim of the study: To test the hypothesis that stopping treatment with ACEi, ARB or a combination of both, compared with continuing on these treatments, improves or stabilises renal function in patients with progressive stage 4 or 5 Chronic Kidney Disease (CKD).

Study design: Open-label randomised controlled trial (RCT).

Sample size: 410 patients will be recruited into the study (205 in each arm) over a 2 year period.

STOP-ACEi Twitter

Join over 200 other Twitter users and Follow us @STOPACEi_trial

Contact details

Trial website:	www.birmingham.ac.uk/STOPACEi
Online randomisation & data entry:	www.trials.bham.ac.uk/STOPACEi
E-mail:	STOPACEi@bham.ac.uk STOP.ACE@nhs.net
Telephone:	0121 415 9133
Fax:	0121 415 9135
Post:	Birmingham Clinical Trials Unit Public Health Building University of Birmingham Edgbaston B15 2TT
STOP-ACEi staff:	Elizabeth Brettell, Renal Team Leader Marie Valente, Trial Coordinator Jamie Godsall, Data Manager

Before you leave

- Slides will be made available online
- Certificates / CPD credits
- Feedback forms
- Expenses forms