



# Outline

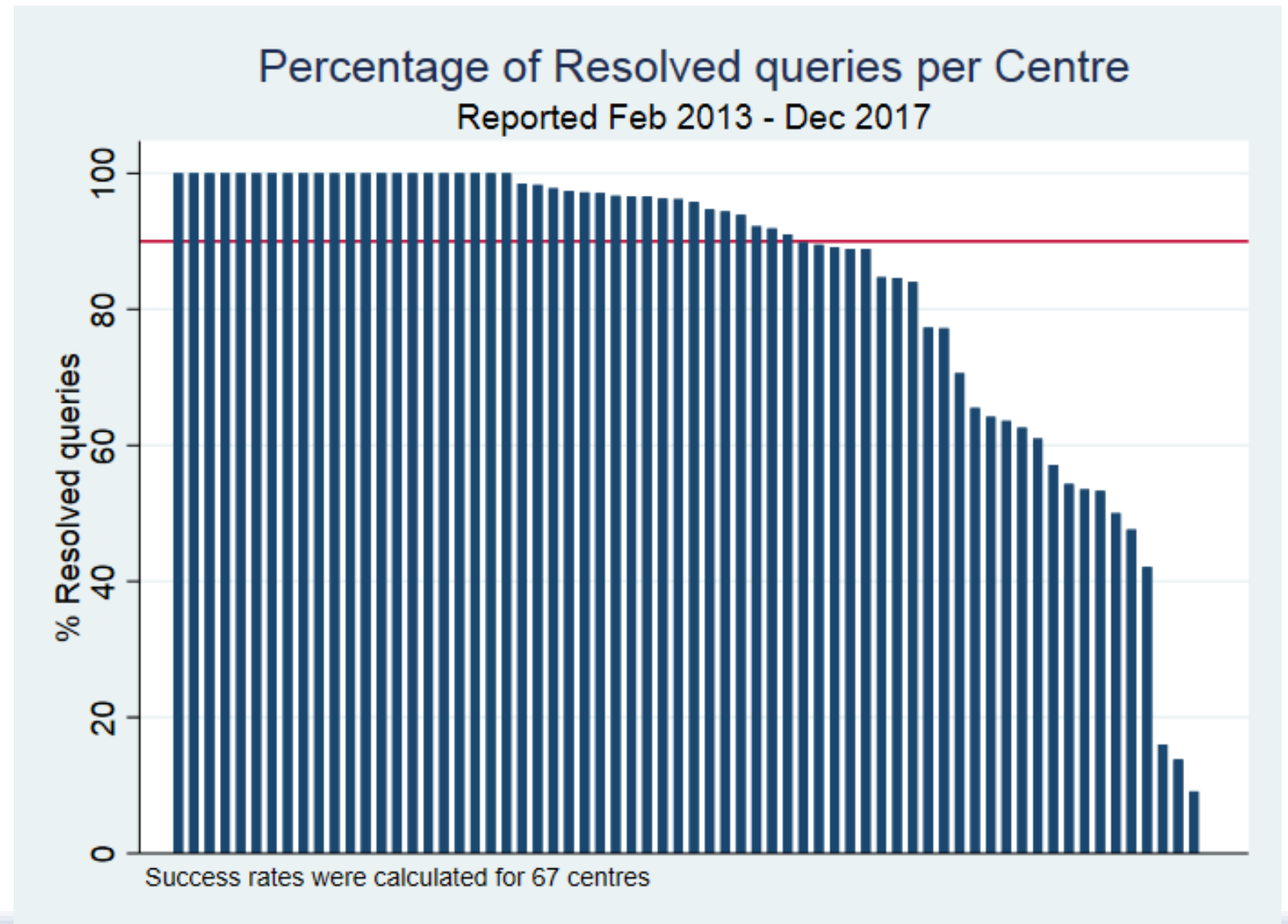
- Data Queries
  - Overview
  - Examples of good/not so good responses
- Data entry
  - Progress so far
  - Reasons for delays & how to resolve
- Database lockdown
  - 18month visit data entered on database
  - Timeline

# Data Queries

- From July to December 2017 → 433 queries created
  - 55% were resolved
  - 75% were created with regards to Visit 4
- Main focus:
  - CRF completion prior to Visit 4 lockdown
  - Update Registration form if patient has withdrawn
  - Checks for duplicate records
  - Investigate inaccuracies

# Overall

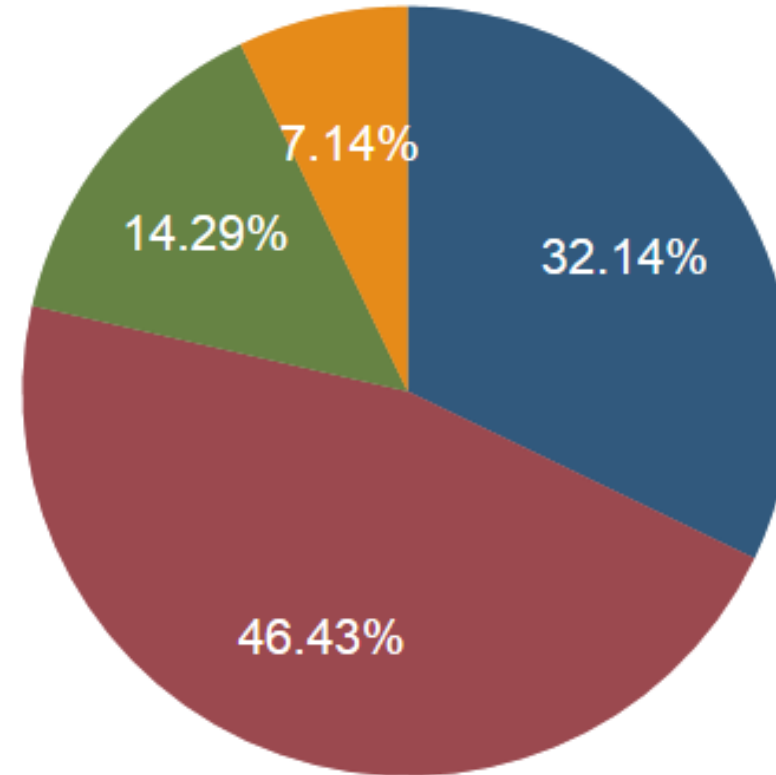
- ❖ 3364 queries have been recorded so far
- ❖ Majority of queries were with regards to Medication (33.6%)
- ❖ So far 60% of all participating centres dealt with  $\geq 90\%$  of their queries
- ❖ Keep in mind; some of the queries have been followed up at least once over time



# Last 6 months

- ❖ Most queries were related to:
  - Form completion (45%)
  - Medication form (43%)  
(when they only referred to details on CRF)

Percentage of Centres with Outstanding queries  
From July to Dec 2017



Frequencies were calculated for 56 centres

# Last 6 months

- Most replies from August onwards
- Identified occasional database issues
- Possible overreporting (e.g. follow-up of older queries)
- CRF completed at clinic (e.g. MoCA) more likely to be entered on time
- Patient forms (e.g. SCOPA-AUT) more likely to be missing if not completed at study visit

# Data Queries

- Best way to deal with a query

After reviewing, click Update

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Centre	ID	Date of query
<input type="text"/>	<input type="text"/>	08/09/2017 <input type="text"/>

Query by	Visit	Form
<input type="text" value="sofia.kanavou@bristol.ac.uk"/>	<input type="text" value="V4"/>	<input type="text" value="Medication"/>

Query (from admin centre)	Enter response to query ----->	Response (by study site)	Corrected on eCRF
<input type="text" value="According to memo at V3 patient was on Rasagiline 1mg OD from 27/1/2014 – 4/2/2014 but stopped. Then according to memo at V4 patient was on Rasagiline 20/02/2013 - 12/09/2013 and then restarted on 01/06/2014. Could you please check and clarify. Thanks."/>		<input type="text" value="on rasagiline 1mg OD from 20/02/2013 but has intermittently stopped this medication on several occasions due to side effects"/>	<input type="text" value="Yes"/>

Last updated by (at study site)	email of person making the latest update	Timestamp (last updated)	Status
<input type="text"/>		08/09/2017	<input type="text" value="Resolved"/>

# Data Queries

- Not so great

After reviewing, click Update

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Centre	ID	Date of query	Query by	Visit	Form
<input type="text"/>	<input type="text"/>	<input type="text" value="02/10/2017"/>	<input type="text" value="sofia.kanavou@bristol.ac.uk"/>	<input type="text" value="V4"/>	<input type="text" value="Medication"/>

Query (from admin centre)	Response (by study site)	Corrected on eCRF
<input type="text" value="At Visit 4 (18 months) this form is missing, please complete. If this cannot be done retrospectively, could you please let me know. Thanks."/>	<input type="text" value="No information is available for this query"/>	<input type="text" value="Yes"/>

Enter response to query ----->

Last updated by (at study site)	email of person making the latest update	Timestamp (last updated)	Status
<input type="text"/>		02/10/2017	<input type="text" value="Outstanding"/>



# Data Queries

- Still good – but (Example I)

After reviewing, click Update

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Centre	ID	Date of query	
<input type="text"/>	<input type="text"/>	<input type="text" value="11/09/2017"/>	
Query by	Visit	Form	
<input type="text" value="sofia.kanavou@bristol.ac.uk"/>	<input type="text" value="V4"/>	<input type="text" value="Medication"/>	
Query (from admin centre)	Enter response to query ----->	Response (by study site)	Corrected on eCRF
<input type="text" value="At Visit 4 (18 months) based on 'Which MAOB-I ?' field, patient is on Rasagiline but dose is missing - please complete. If this information cannot be retrieved retrospectively, please let me know. Thanks."/>		<input type="text" value="1 mg once daily - updated by"/>	<input type="text" value="Yes"/>
Last updated by (at study site)	email of person making the latest update	Timestamp (last updated)	Status
<input type="text"/>		11/09/2017	<input type="text" value="Resolved"/>
<input type="button" value="Update"/> <input type="button" value="Back"/>			

# Data Queries

- Still good – but (Example II)

After reviewing, click Update

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Centre	ID	Date of query
<input type="text"/>	<input type="text"/>	<input type="text" value="08/09/2017"/>

Query by	Visit	Form
<input type="text" value="sofia.kanavou@bristol.ac.uk"/>	<input type="text" value="V4"/>	<input type="text" value="QUIP, CON, SCOPA-AUT and UPDRS Patient"/>

Query (from admin centre)	Enter response to query ----->	Response (by study site)	Corrected on eCRF
<input type="text" value="At V4 this form is missing, please complete. If this form cannot be filled in retrospectively, please let me know. Thanks."/>		<input type="text" value="Completed"/>	<input type="text" value="Yes"/>

Last updated by (at study site)	email of person making the latest update	Timestamp (last updated)	Status
<input type="text" value="sofia.kanavou@bristol.ac.uk"/>		08/09/2017	<input type="text" value="Resolved"/>

# Data Queries

- Goal → reduce amount of queries reported

After reviewing, click Update

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Centre	ID	Date of query	When the answer is obvious		
<input type="text"/>	<input type="text"/>	<input type="text" value="24/08/2017"/>			
Query by	Visit	Form			
<input type="text" value="sofia.kanavou@bristol.ac.uk"/>	<input type="text" value="V4"/>	<input type="text" value="Medication"/>			
Query (from admin centre)	Enter response to query ----->	Response (by study site)	Corrected on eCRF		
<input type="text" value="At V4 (18 months) Pramipexole salt dose is 260mg. Could you please check and correct. Thank you."/>		<input type="text" value="The correct dose is 260mcg or 0.26mg"/>	<input type="text" value="Yes"/>		
Last updated by (at study site)	email of person making the latest update	Timestamp (last updated)	Status		
<input type="text"/>		24/08/2017	<input type="text" value="Resolved"/>		

# Data Queries

- Goal → reduce amount of queries reported

After reviewing, click Update

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Centre	ID	Date of query			
<input type="text"/>	<input type="text"/>	<input type="text" value="24/08/2017"/>			
Query by	Visit	Form			
<input type="text" value="sofia.kanavou@bristol.ac.uk"/>	<input type="text" value="V4"/>	<input type="text" value="Medication"/>			
Query (from admin centre)	Enter response to query ----->	Response (by study site)	Corrected on eCRF		
<input type="text" value="At V4 (18 months) patient is on Amantadine of 200mg twice per day, where 'any extra' field says '1'. Something like 100 or 200 would be expected. Could you please check that field and correct. Thank you."/>		<input type="text" value="Recorded on memo: Extra dose of Amantadine is 100 mg"/>	<input type="text" value="No"/>		
Last updated by (at study site)	email of person making the latest update	Timestamp (last updated)	Status		
<input type="text" value="sofia.kanavou@bristol.ac.uk"/>		24/08/2017	<input type="text" value="Resolved"/>		

When the answer might be recorded elsewhere on the form (e.g. memo)

# Data Queries

- How to answer a query online:

- ❖ Reply to the query (e.g. completed)
- ❖ Select “Yes” if you applied any changes on the e-CRF
- ❖ Choose your e-mail from the drop-down list (i.e. last updated by)
- ❖ Select “Resolved” & click “Update” to complete

After reviewing, **click Update**

← [Search Again](#)

Centre	ID	Date of query
<input type="text"/>	<input type="text"/>	<input type="text" value="02/10/2017"/>

Query by:  Visit:  Form:

Query (from admin centre)

Enter response to query ----->

**Response (by study site)**

**Corrected on eCRF**

**Last updated by (at study site)**

email of person making the latest update:  Timestamp (last updated):  **Status**

Record 9 of 403

sofia.kanavou@bristol.ac.uk | Sofia Kanavou | Query

# Data Entry

- Four centres with significant delays
  - Contacted personally & offered to help
  - Only one asked for further details; preferable resolution over the phone/e-mail rather than the online querying system
- Data entry from Bristol
  - Pros: Helpful & efficient
  - Cons: Caution when e-mailing patient information (i.e. scanned CRF)

# Data Entry

- Focused on 18month visit lockdown
  - Initial date: September 2017
  - Final date: January 2018
- Any new entries or updates will not be included in the V4 dataset
- Overview of V4 data

# Database lockdown

- Visit 4 (18 months) lockdown → Challenges
- Data collection at V4

<b>CRF</b>	<b>Overall</b>
Medication	1721 / 2000
MoCA	1724 / 2000
UPDRS Clinician	1727 / 2000
QUIP / Constipation / SCOPA-AUT / UPDRS patient	1673 / 2000
PDQ8 / EQ5D / ESS / RBD / HADS	1681 / 2000
NMSS / PDSS	1681 / 2000

Note: number of forms entered reflects the raw data (withdrawn patients included)



# Database lockdown

- Timeline for future follow – up visits
- Based on first/last date of visit at the clinic
  - Recorded in November 2017 (Medication form)

Follow-up visit	First visit	Last visit	Possible dates of Database Lockdown
<b>18 months (V4)</b>	<b>10/01/2013</b>	<b>04/12/2016</b>	<b>12/01/2018</b>
24 months (V5)	26/03/2013	05/12/2017	01/03/2018
30 months (V6)	10/01/2014	01/12/2017	01/05/2018
36 months (V7)	04/01/2015	04/12/2017	01/07/2018

# Conclusion

- Data Queries → moving forward
  - Goal to reduce no. of queries reported
  - Address challenges with querying system
- Data entry:
  - Stick to the Timeline
  - Best way to reduce delays → submit forms at study visit