

Tracking Parkinson's

A Brief Summary of Study data

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Outline

- Data collection
 - Form completion rates
 - Withdrawals & cases with change in diagnosis
 - Common errors / things to avoid
- Queries
 - Resolution rates
- Database lockdown
 - Timeline

Data collection

❑ Form completion rates*

Locked-down visits;
no further changes are
expected up until V7

Extended follow-up
(ongoing)

Follow – up visits	%CRFs on Database (inc. withdrawn)	%CRFs on Database (exc. withdrawn)
Baseline (V0/1)	100%	100%
6 months (V2)	93.75%	97.5%
12 months (V3)	90.9%	98.3%
18 months (V4)	86.45%	97.85%
24 months (V5)	79.3%	95.2%
30 months (V6)	74.9%	93.8%
36 months (V7)	70.7%	92.6%
42 months (V8)	49.3%	80.65%
54 months (V9)	41.25%	71.8%
72 months (V10)	7.1%	14.2%

*Rates are calculated based on the Medication forms

Data collection

❑ Withdrawals

- 50.1% of recruited patients have withdrawn from the study (06/05/19).
- Out of 1002 withdrawn subjects:
 - 817 (81.5%) have all relevant information recorded on the Registration form.
 - 18.4% missing withdrawal date– all come from 10/68 Centres (14.7%).
 - 34 (3.4%) had a change in their initial diagnosis
 - Approximately 1/3 of withdrawals are due to patients decline of follow-up extension or Site's difficulty to support it

Data collection

❑ Withdrawals

Reasons (N= 1002)	N (%)
Change in diagnosis	34 (3.4%)
Developed dementia	10 (1%)
Patient died	124 (12.4%)
Did not consent to study extension	111 (11.1%)
Entered nursing/residential home	9 (0.9%)
Intercurrent illness	75 (7.5%)
Moved out of area	11 (1.1%)
Patient choice	177 (17.6%)
Site closed	218 (21.75%)
Too disabled to attend	11 (1.1%)
Withdrew consent	32 (3.2%)
Other	190 (18.95%)

968 cases
(96.6%)

Data collection

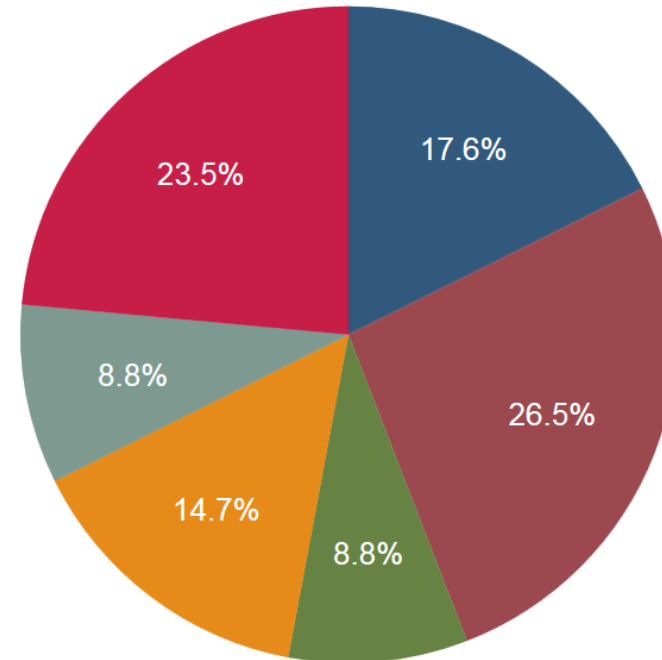
❑ Change in diagnosis

“Other diagnosis” category includes:

- *MS*
- *Corticobasal degeneration*
- *Post polio syndrome*
- *Spinal cord syndrome*
- *SWEDD*
- *SWEDD subdural haematoma*
- *SWEDD and cerebrovascular tremor*

Alternative diagnosis

Based on 34 cases



PSP

Vascular Parkinsonism

Essential or dystonic tremor

MSA

Unknown (definitely not PD)

Other diagnosis

Date of data extraction: 06/05/2019

Data collection

❑ Common errors / things to avoid

- Some interesting cases initially recorded under “Other” reasons:
 - *Patient finds study unacceptable*
 - *Patient not on Parkinson’s medication*
 - *Patient choice – not entering study extension (2 cases)*
 - *Unspecified diagnosis change*
 - *Misdiagnosed - patient does not have PD*

Data collection

❑ Common errors / things to avoid

- Cases initially recorded under “Other” reasons:
 - *Patient finds study unacceptable*
 - *Withdrew after Baseline visit; would be good to have a few more details on memo (i.e. why patient found the study to be unacceptable?)*
 - *Patient not on Parkinson’s medication*
 - *This could trigger a re-evaluation of patient’s diagnosis, but should not be a reason to withdraw from study*
 - *Patient choice – not entering study extension (2 cases)*
 - *Subject I: Patient had already completed Visit 10 – conflicting information*

Data collection

❑ Common errors / things to avoid

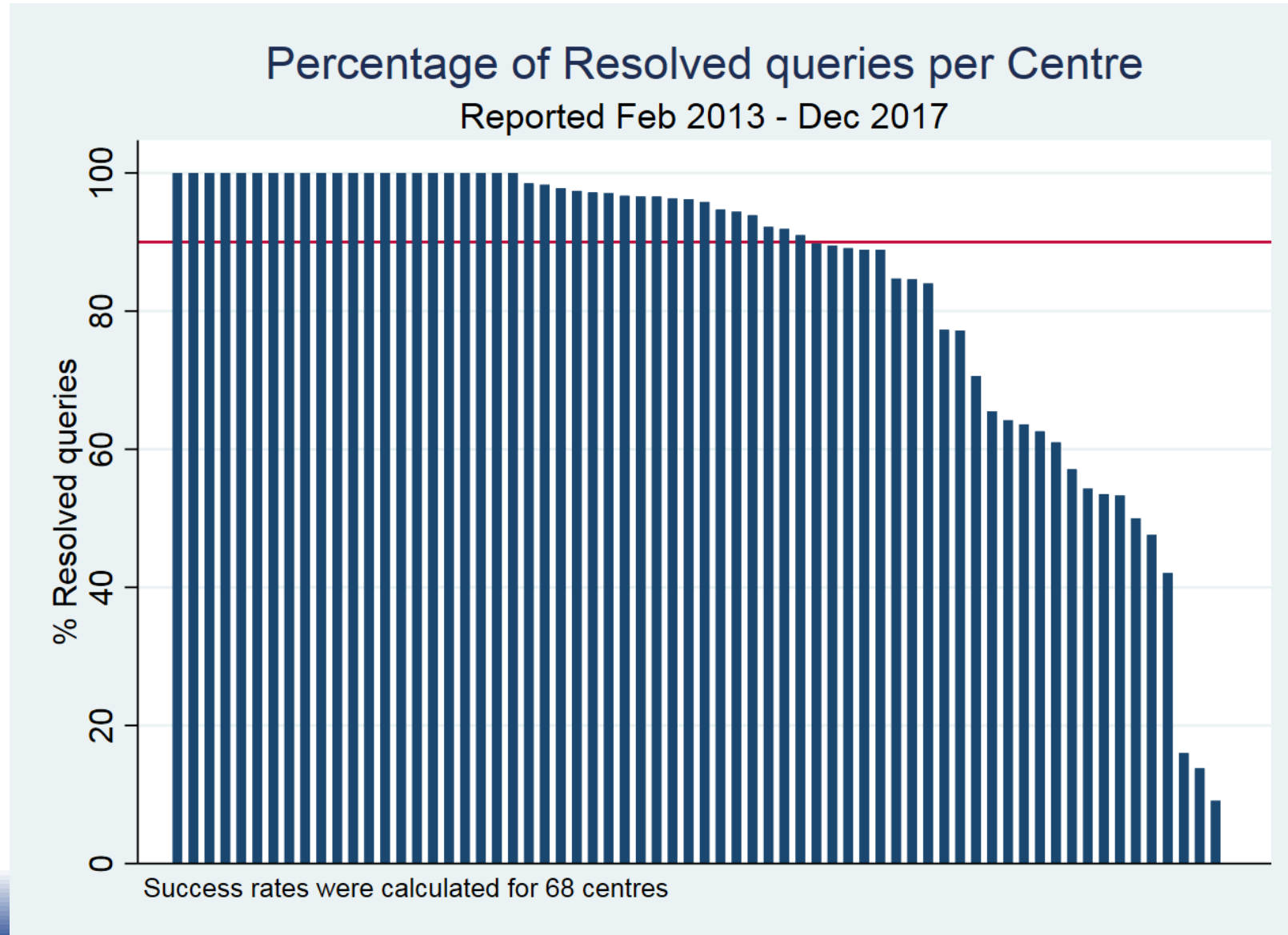
- Cases initially recorded under “Other” reasons:
 - *Patient choice – not entering study extension (2 cases)*
 - *Subject II: Patient had a new diagnosis recorded on the form; reason for withdrawal should have been “change in diagnosis”*
 - *Unspecified diagnosis change*
 - *Even with unspecified new diagnosis, this should have been recorded as “change in diagnosis”*
 - *Misdiagnosed - patient does not have PD*
 - *This should have been recorded as “change in diagnosis”*

Queries

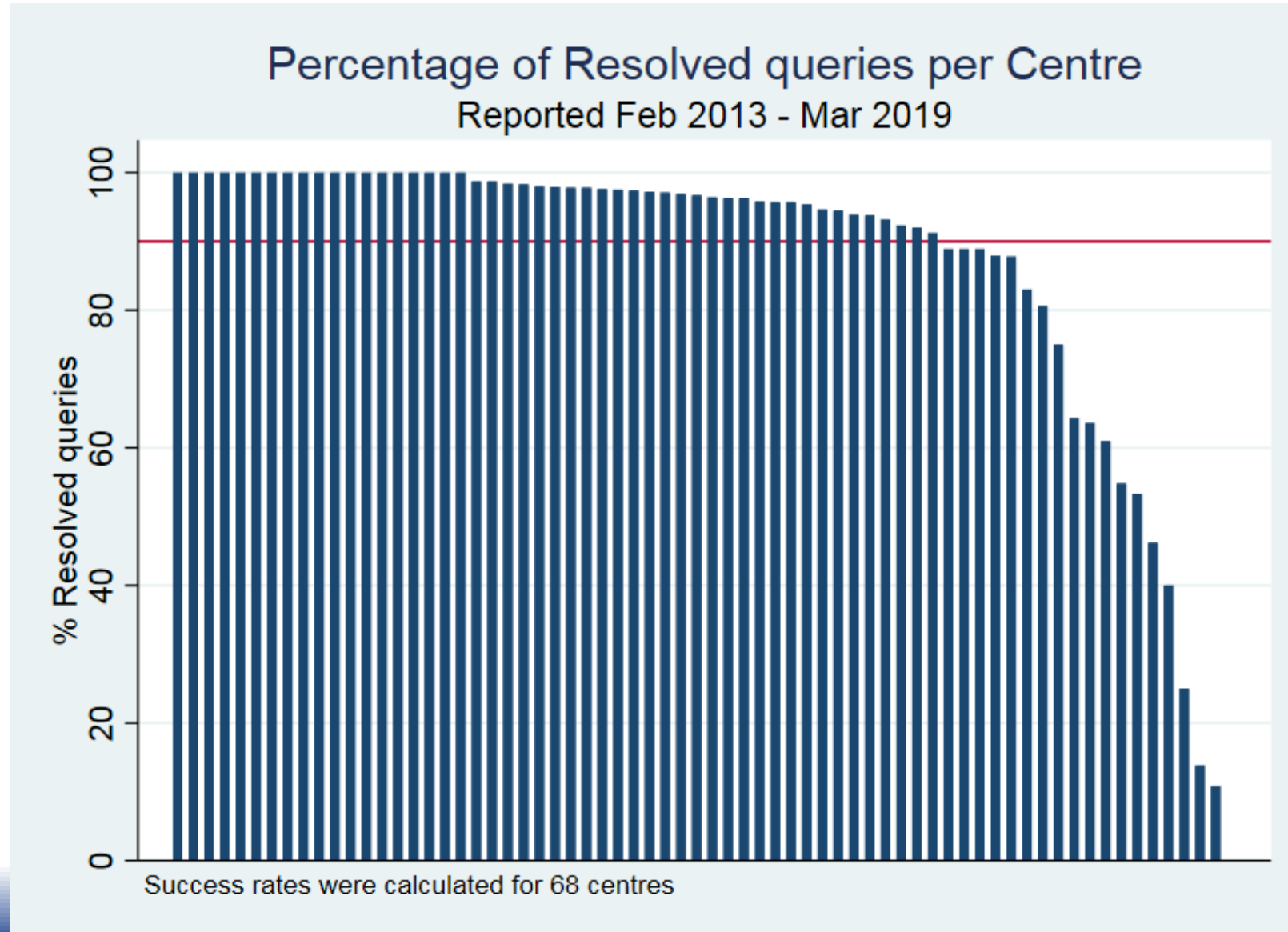
❑ Resolution rates

- 3616 queries have been recorded so far - 90.4% have been resolved.
- Majority of queries were with regards to Medication (34.9%), Diagnostic factors (9.3%), Registration (7.4%) and UPDRS Clinician form (7%).
- So far 70% of all participating centres dealt with $\geq 90\%$ of their queries.

Queries



Queries



Queries

❑ Last 2 years in the study

- July 2017 - March 2019 → 592 queries entered on database
 - 66.6% were resolved
 - Out of 198 outstanding queries:
 - 35.9% refer to 18-month visit
 - 17.2% refer to 36-month visit
- Queries focus mostly on:
 - Medications (46.6%); UPDRS Clinician (12.8%); MoCA (12.5%)

Database lockdown

□ Timeline

Follow-up visit	First visit*	Last visit*	Database Lockdown
18 months (V4)	03/05/2013	01/12/2016	12/01/2018
24 months (V5)	21/01/2014	14/02/2018	01/03/2019
30 months (V6)	06/06/2014	06/06/2018	01/03/2019
36 months (V7)	05/01/2015	12/09/2018	01/03/2019

*Taken from Medication form extracted in March 2019

Database lockdown

□ Timeline

Follow-up visit	First visit*	Last visit*	Database Lockdown
18 months (V4)	10/01/2013	04/12/2016	12/01/2018
24 months (V5)	26/03/2013	05/12/2017	01/03/2019
30 months (V6)	10/01/2014	01/12/2017	01/03/2019
36 months (V7)	04/01/2015	04/12/2017	01/03/2019
42 months (V8)	22/09/2015	(ongoing)	01/09/2019
54 months (V9)	29/06/2016	(ongoing)	01/03/2020
72 months (V10)	17/01/2018	(ongoing)	01/03/2021

Done; datasets annually amended based on any updates recorded throughout the year

Estimated (likely to change)

*Taken from Medication form extracted in March 2019

Summary

- Based on Medications forms recorded on Database
 - $\geq 90\%$ forms entered in 3 years of follow-up
 - similar rates expected for forms completed at the clinic (*UPDRS*, *MoCa*)
 - Rates drop in follow-up extension
 - Around 1/3 did not participate after 3-year follow-up

Summary

- Withdrawals & changed diagnosis always recorded on relevant fields the Registration form
- Queries are being handled more quickly
 - Few specific centres that are not very responsive
- Lock-down of 3 year follow-up period
 - Data will be reviewed and amended annually
 - Current data version 1