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AVATAR-AF: Getting to the heart of data management for analysis
(5 simple rules to follow to ensure data integrity)

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HELP! The last patient visit is scheduled for next week yet the team want the data cleaned, the database locked and the analysis completed and verified for abstract submission in 50 days.
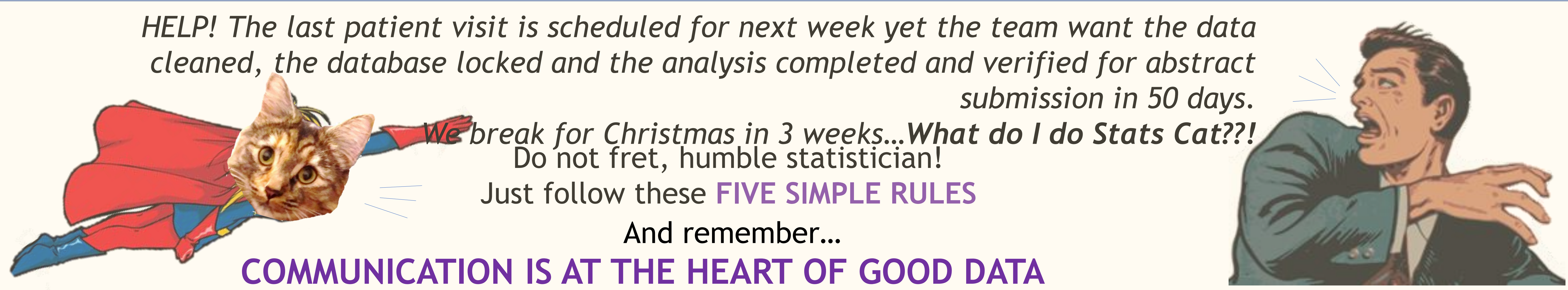*We break for Christmas in 3 weeks…What do I do Stats Cat??!*

Do not fret, humble statistician!
Just follow these FIVE SIMPLE RULES
And remember…
COMMUNICATION IS AT THE HEART OF GOOD DATA MANAGEMENT

2. Forge positive relationships with study centres

- Has a positive effect on recruitment
- Potentially reduces data entry errors
- Reduces time to resolve data queries
- Removes the risk of emails being lost and unanswered due to staff leave/turnaround

It **allows the site to feel like an integral part of the study:**

1. Embrace efficient database design

There is always a desire to ensure that as much information is collected as possible. However, it is also important to ensure that each piece of data has a valid reason for being recorded. **Quality, not quantity is key!**

COMMUNICATION

3. Plan ahead! Schedule & include milestones

Discuss publication and conference plans early with your chief investigator!
Milestones may include:

1. Data cleaning of xx% patients
2. Last patient visit
3. Data cleaning of all patients
4. Hard/final lock of data base
5. Completion of analysis for abstract
6. Validation of analysis results for abstract
7. Checking of abstract draft

4. Utilise time with the DSMB (and TSC) to discuss issues

If you have a DMEC/DSMB within your trial, treat this as an opportunity to raise queries. If something unexpected is happening within the trial data, do not be afraid to raise this to ensure **any issues can be resolved before it escalates into something more serious**.

5. Don't be afraid to escalate unexpected events

In working within clinical trials you are surrounded by **colleagues with a wealth of experience and information**. These institutions have structures which allow you to escalate difficult queries which may require input at a higher/senior level. Take advantage of this to ensure that the situation will not return when you no longer have time to find a solution.

HOW WE USED THE RULES WITHIN AVATAR-AF

Plan ahead! Schedule & include milestones
Three pieces of information allowed us to submit at EHRA 2019:
- Deadline for abstracts was **08 Jan 2019**
- Database was locked on **26 Nov 2018**
- The plan to submit to EHRA was agreed in Spring 2018

The final point allowed us to schedule routine, fortnightly data meetings over the summer. This ensured that data cleaning post final subject visit was minimal thus vastly reducing the time to final database lock.

Forge positive relationships with study centres
The AVATAR-AF trial held regular investigator meetings which allowed representatives from each site to meet up alongside the study team to discuss trial progress and issues in a relatively informal setting. This had a very positive effect on all of the sites such that by completion, every site stated hey were willing to work with the CI again. Likewise, data queries were completed regularly and on time.

Utilise time with the DSMB to discuss issues
The AVATAR-AF DSMB met approximately every 6 months. One issue soon became apparent - the event rate in the AVATAR arm was lower than expected. This was potentially an issue and questions regarding power and increasing sample size were soon raised. In noticing this situation early we were able to monitor the situation over many meetings. It was agreed that as the primary analysis between AVATAR and anti-arrhythmic drug arms would not be negatively affected the decision was made to proceed as planned.

AVATAR-AF – A brief guide