



How Do You Determine # SDTM's ADAMs and TLF and it's impact on Outsourcing?

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Introduction

Reduce costs



=> High value activities.

SDTM's + # ADAM's + # TLFs

Who drives this figure?



Accuracy in prediction & control?

Company variations. Why?

Introduction

Why is this Happening?

Should it be happening?

Do we understand the cost and can it be managed?

Consequences of Incorrect Estimation

Internal

Uncontrollable costs:

- the primary goal remains report study as accurate and fast as possible

Incorrect allocation of resource

- quantity
- type



Resulting in Internal pressure to speed up.

- On-boarding expensive talented resource not familiar with study
 - immediate decrease in efficiency as knowledgeable resource taken away from producing to teaching.
 - Expensive!

Work overtime

- **Fatigue:** "school-boy errors".
- **Becomes an expectation:** Benchmark setting.



Consequences of Incorrect Estimation

If outsourced

Out of Scope

- **COST, COST, COST** at a time when you least want to be taking about cost.
- Incorrect resource estimations will surface earlier in a CRO.



Last Minute unplanned requests / Accelerations

- Cost as resource leads search for resource.
- Cost as new resource familiarises themselves with the study.

Where Are We Now In the Industry?

Methods 1

**SDTM,
ADAM &
TLF
Estimation
=>**

**Based on internal
benchmarks**

BUT : No “outside in”
estimation.

e.g Last CVM phase 3 study was about 400 TLFs
therefore the next study is about the same

Where Are We Now In the Industry?

Methods 2

TLF

Estimation

- Internal benchmark
- Range but derived from where?

Driver

- Statistician
- Programmer
- Clinician/Medic " it's all push button anyway right? "
- PM

Where Are We Now In the Industry?

Methods 2

ADAM

Estimation

- Flat rate
- Benchmark rate
- Function of SDTMs

Driver

- Statistician
- Programmer
- Standards Group
- Resource lead

Where Are We Now In the Industry?

Methods 2

SDTM

Estimation

- Flat rate
- Benchmark rate
- Function of # unique CRFs plus # vendors

Driver

- Statistician
- Programmer
- Standards Group
- DM

Where Are We Now In the Industry?

Methods 3 - Complexity

Unique

Creating for the first time

Repeat

Taking an already created TLF but sub-setting(e.g demography by gender).

Re-run

Changing no code but re-running the output with new data.

Where Are We Now In the Industry?

Methods 3 Complexity



TLF

- Safety
- Efficacy

Where Are We Now In the Industry?

Methods 4 – Complexity

Complexity Of SDTM ADAM, TLF

- Low
- Medium
- High
- Very High

Control

- Medic free hand.
- Statistician advising medic.
- Range based on historical data(could be problematic if internal benchmark only).
- Limits which need approval from management if exceeded.
- Programmer raises the issues when resource supplied are too minimal. => worst case scenario.

Cost per TLF.

- Denominator: Unique, repeats, re-runs.

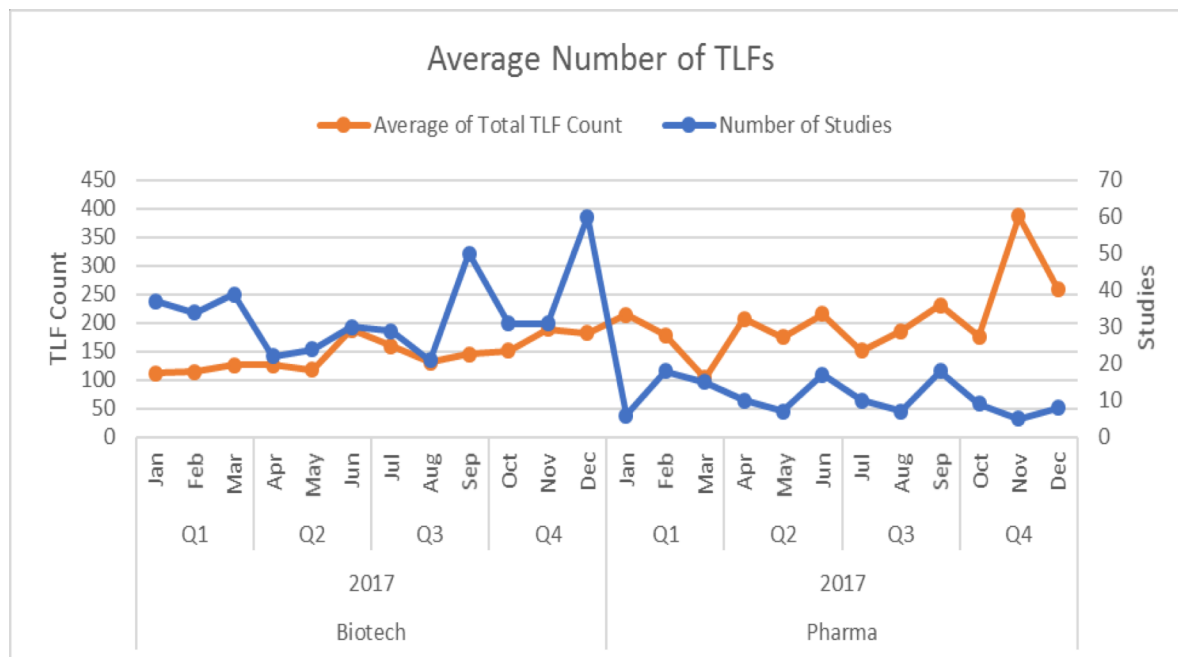
Company TLF Variance Examples

Not claims => designed to stimulate discussion as opposed to be a statement.

Data sampled from PPD bid studies database 2017

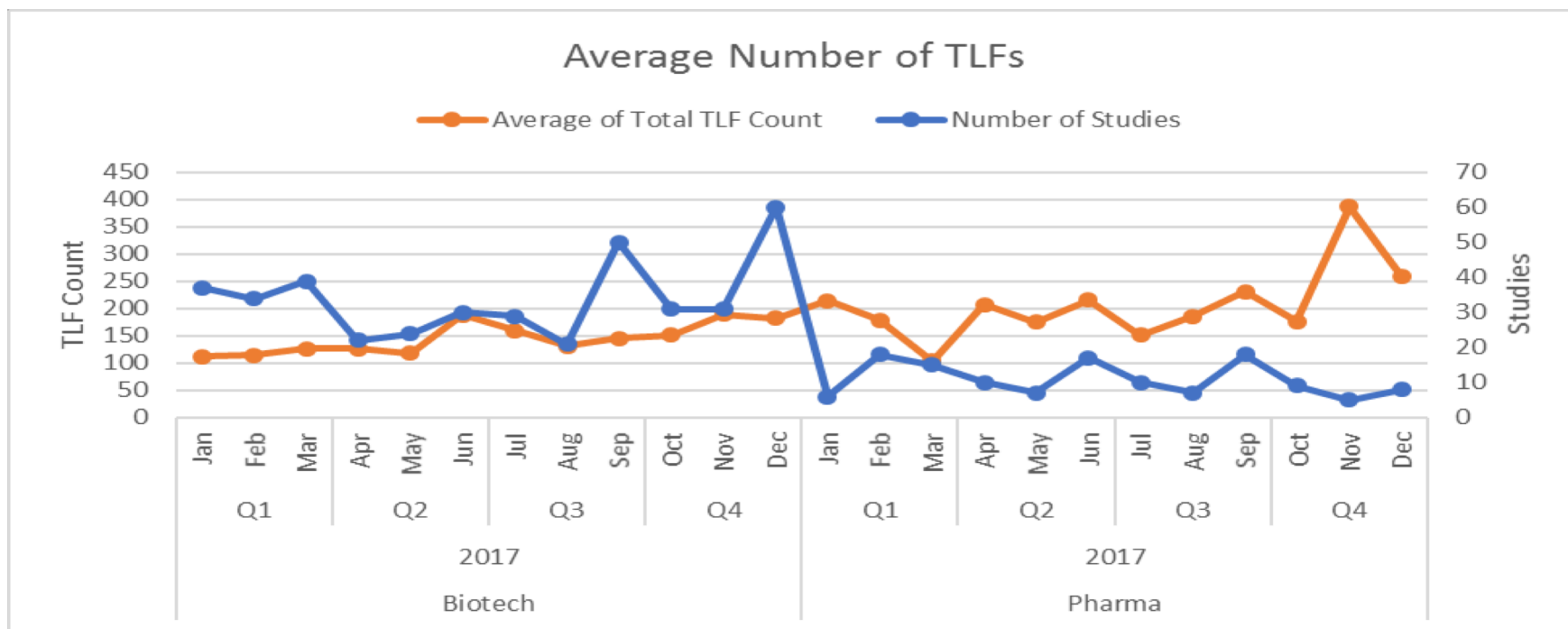
How to read the graph.

- Brown = average # TLFs
- Blue = # of studies
- By Biotech and Pharma



Company TLF Variance Examples

Average number of TLFs for all TA's

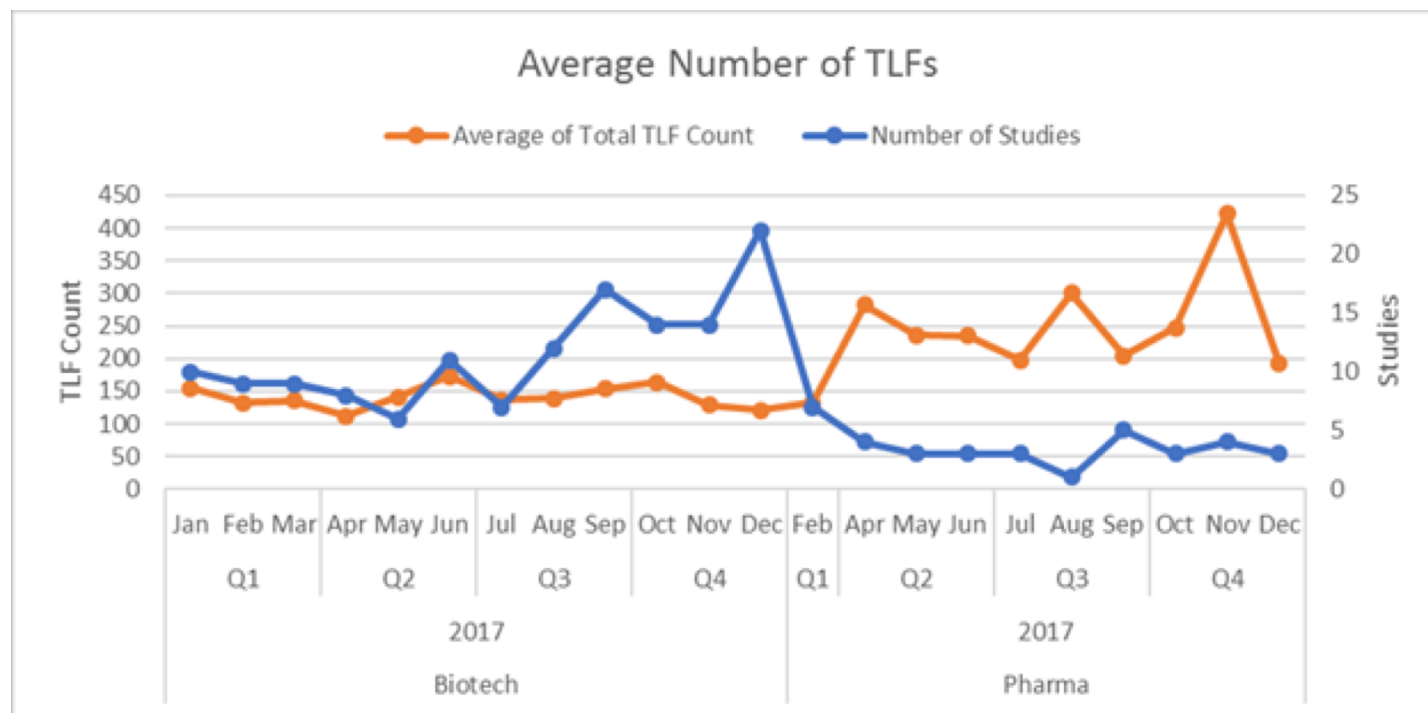


Little inference can be drawn, high level of variability

Biotech slightly less than pharma.

Company TLF Variance Examples.

Average number of TLFs for all TA's for Phase II

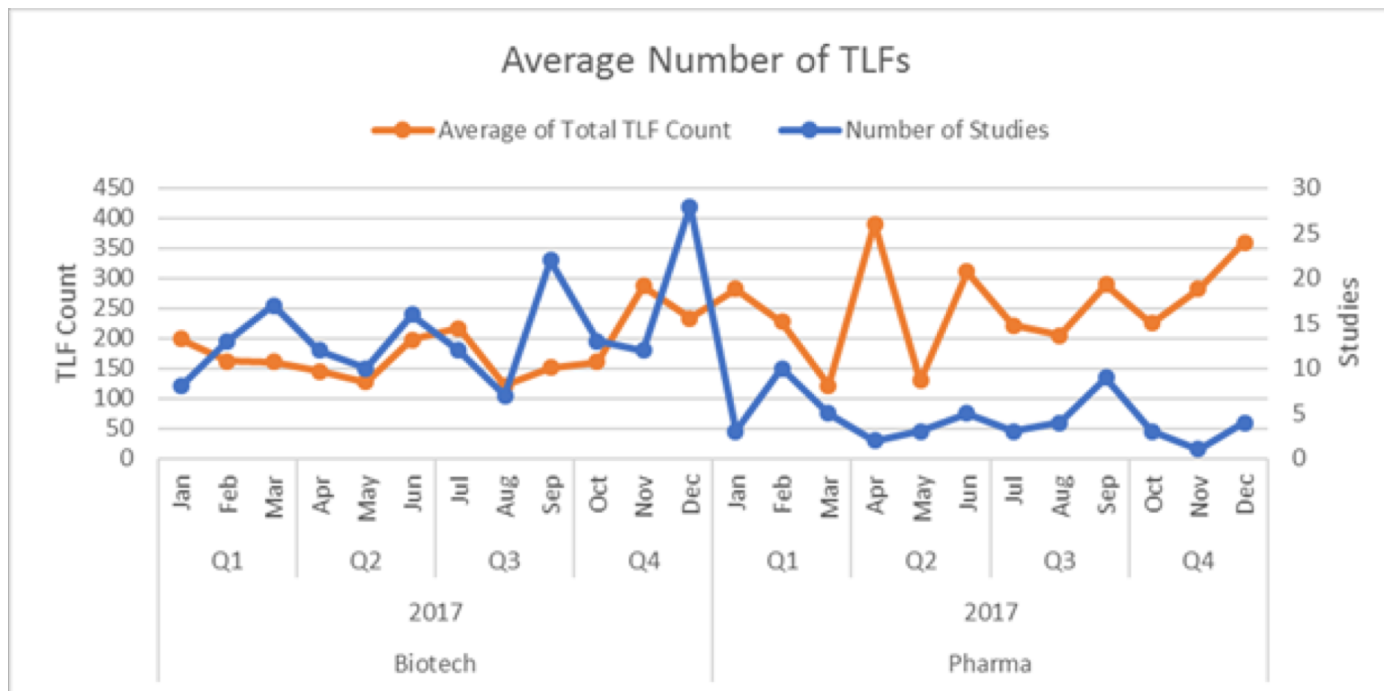


Pharma companies higher.

High variability in pharm but this is all TA's.

Company TLF Variance Examples

Average number of TLFs for all TA's for Phase III



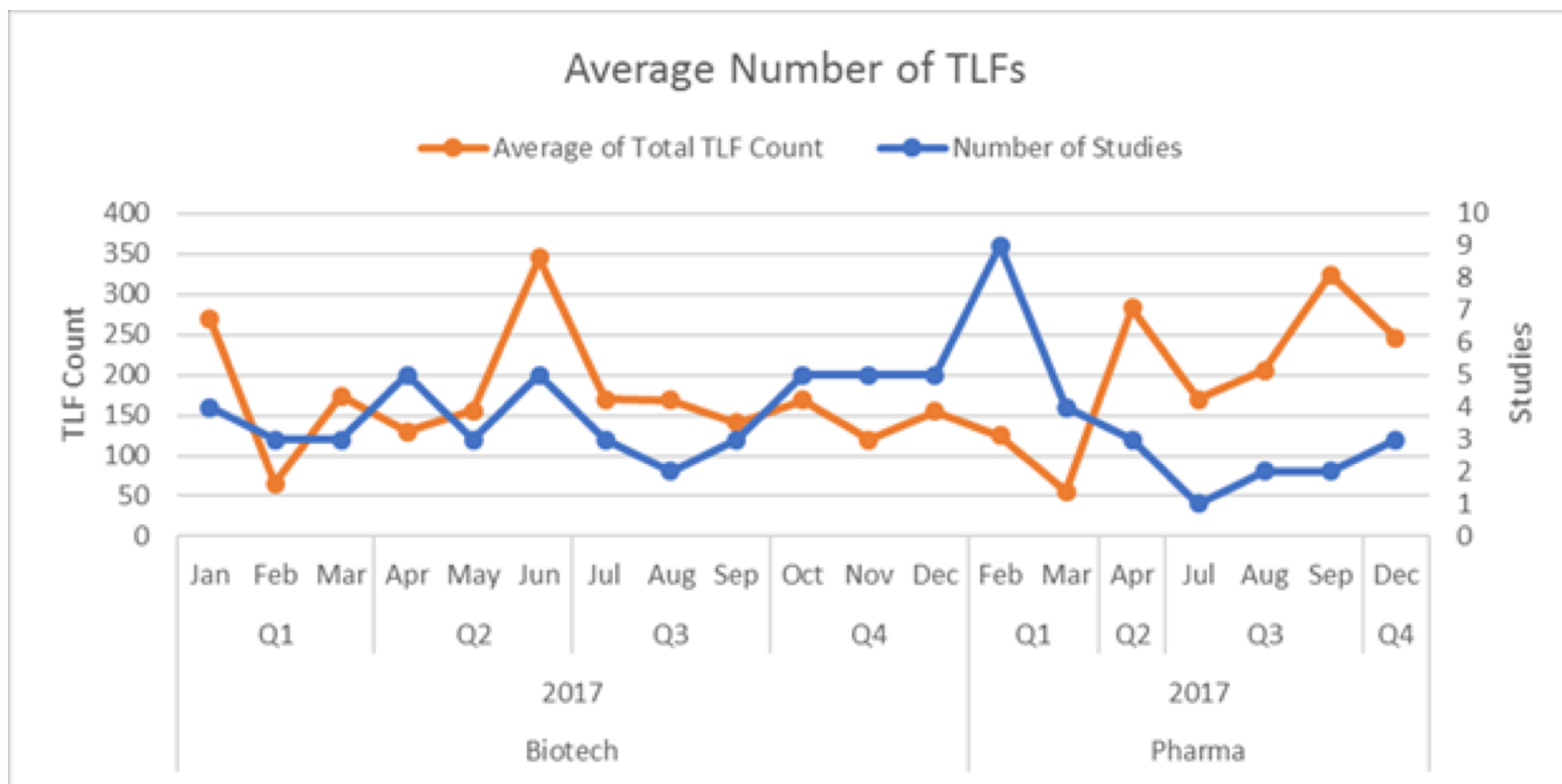
Pharma companies higher.

High variability in pharm but this is all TA's.

Higher counts for phase 3 compared to phase 2

Company TLF Variance Examples

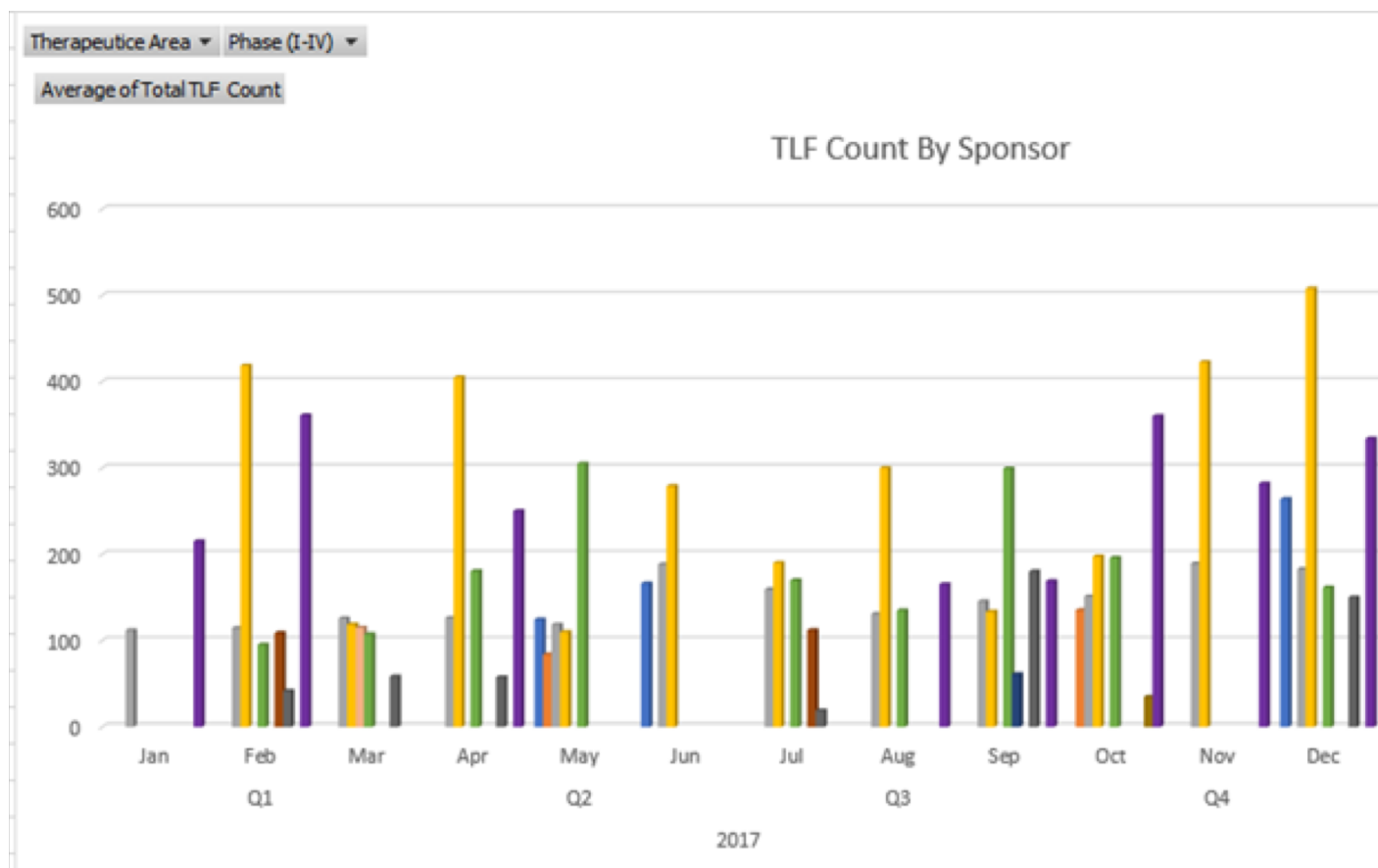
Average number of TLFs all IRD for phase 2&3



Pharma companies higher than Biotech

Company TLF Variance Examples

TLF Count by Sponsor all TA's, all phases.

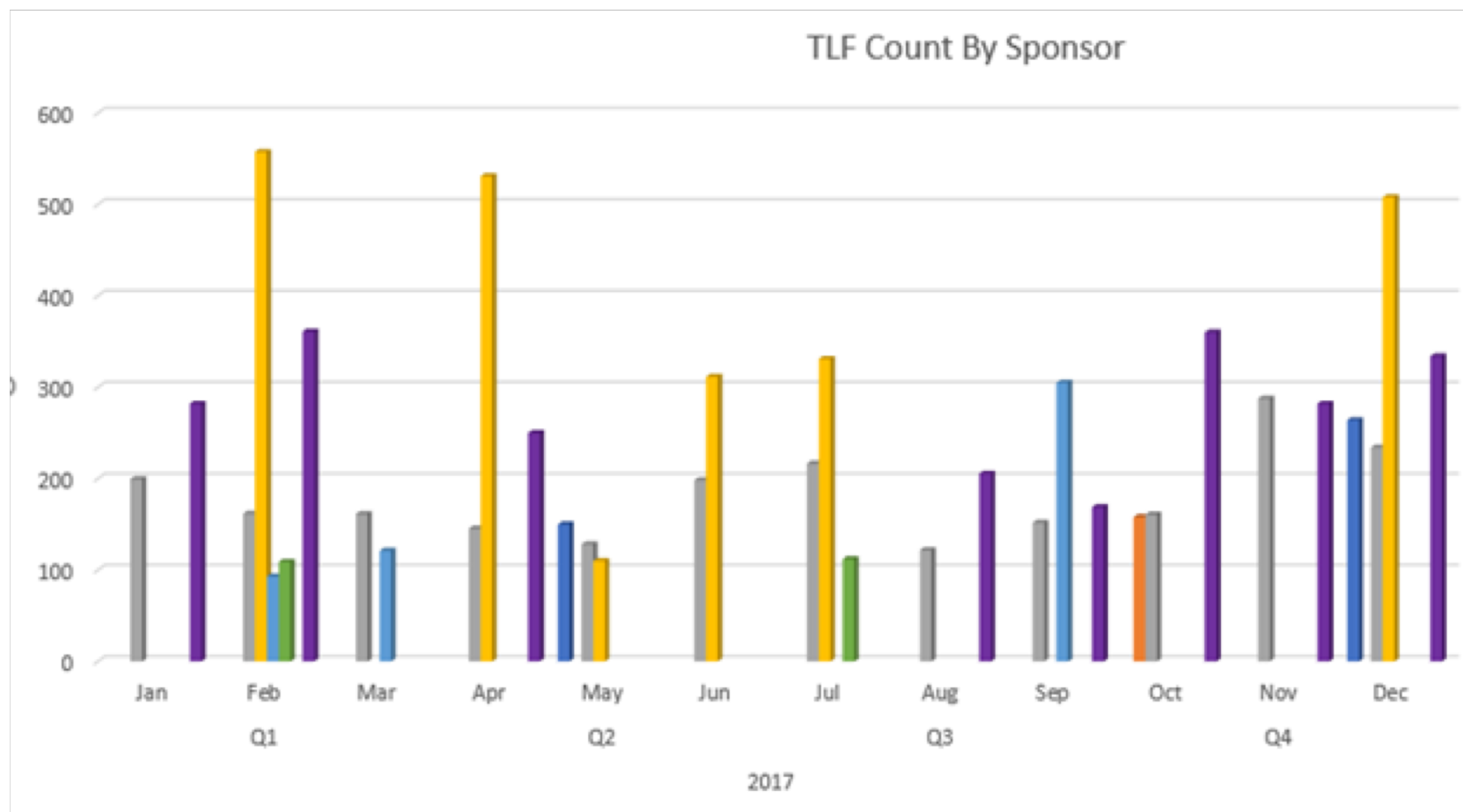


Biotech(grey) smaller than Pharma

Yellow & Purple companies consistently high, why is that?

Company TLF Variance Examples

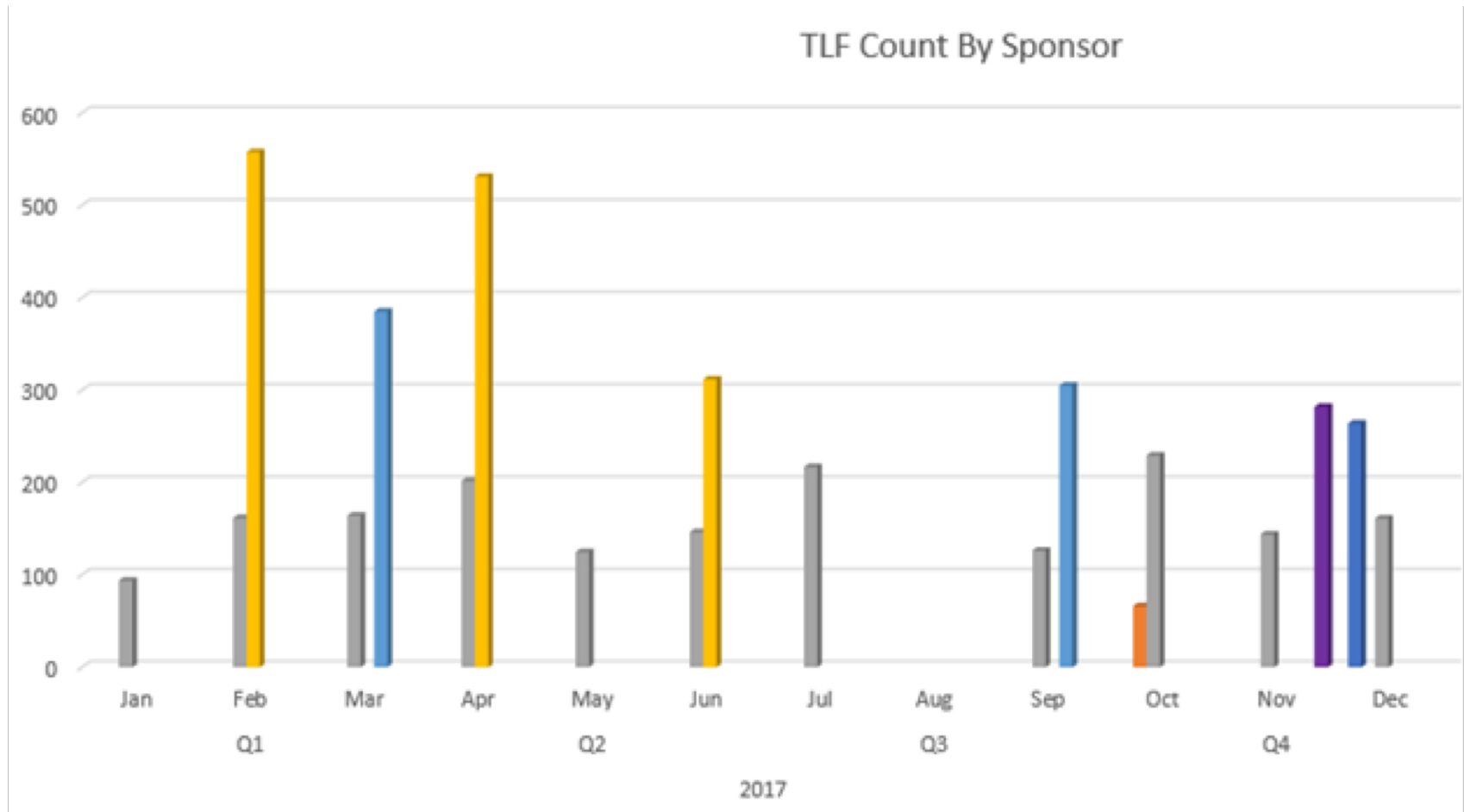
TLF Count by Sponsor all TA's, phase 3



Yellow & purple companies have high counts.

TLF Variance Examples

TLF Count by Sponsor Gen Med phase 3



Yellow & light blue companies have high counts.

Company TLF Variance Examples

Why is this Happening?

Should it be happening?

Do we understand the cost and can it be managed?

Conclusion

- A potential **cost saving** exercise is **paying closer attention to the estimations regarding # SDTM's, ADAM's and TLFs**.
Incorrectly estimating these can lead to incorrect resourcing or dreaded “out of scope” discussions if out-sourced.
- Too often the realization of incorrect estimations is **only realized when the programming team have inadequate resources** to complete a task which will then lead to spiraling costs to operationally achieve the original goal.
- **Different methods of estimation are used by companies** and with different levels of control/sense check.
- The **functional driver of the number TLF's can be the medic and/or the statistician**.
- **Biotech companies appear to have lower TLF counts than pharma companies**, why is that?
- **Some companies have extremely high TLF counts** compared to the mean why is that?

Recommendations

- Scope **discussions must take place concerning number of SDTMs, number of ADAMs number of TLFs before study starts** to avoid incorrect resource estimations or painful “out of scope” discussions if outsourced, ideally level of complexity is considered at least for TLFs.
- **collect historical data** regarding number of SDTM’s, Adam’s and TLFs per TA per phase.
- **A range is developed** for #TLFS per TA/Phase and if these are **exceeded they should be discussed with management** for verification.
- The **lead programmer should be invited to give an opinion** on estimations, resource needs and calculations, cross check with team “actually doing the work”.
- Maybe an **independent body such as PHUSE should collect a database of these figures?**
- **Research why Biotech companies appear to have lower counts compared to Pharma.**

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Questions...

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