IVDR Implementation

Thank you!

Attendees for coming and for your participation

Our conference host AMDM for putting this together

Sarah P. who put my name forward as speaker

The Muwekma Ohlone Tribe on whose unceded land we're gathered

How We'll Spend the Next 30 Minutes

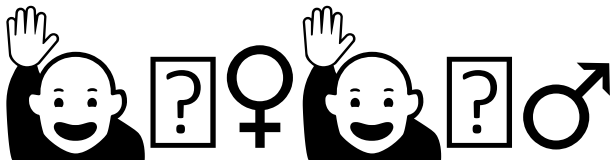
1. Room Survey

2. A Few Nota Benes

3. Some Key Implementation Steps for Industry

ASSUMPTION

No one will survive for years with a product free from design changes, so we're going with 2022 being a "hard" date.



Raise your hand if your company has done an IVDR Gap Assessment.

How many started the assessment with the Performance Evaluation Report?

How many started with the PER and realized they weren’t that bad off?

How many fixed the PER and pretty much stopped there?

Your PER Is Probably Fine ….. Really

Traditional	Public and Field Data	Closing Small Gaps
Novel	Market Creation	KOL and Market Adoption
New to Review	Welcome!	Good Luck!

Your TF Is Probably Not Fine ….. Really

Your Science may be in order, but what about the rest of your Technical Documentation?

Existing sections need revision. There will be new sections. Some TFs need major overhaul.

Risk

Comparison to State of the Art

PSUR

DoC

Economic Operators

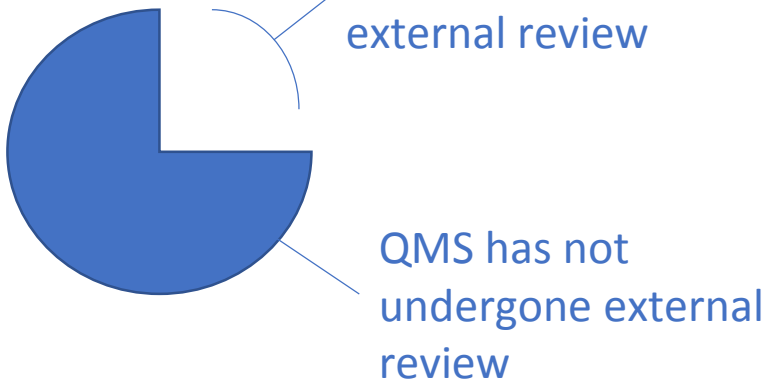
PMSR

Don’t Fear the Marketing Department

REVOLUTIONARY IDEA

the Technical File is a **marketing document** and needs to be *brought in line* with other marketing material

H A N G M _ N



Your QMS will be the death of you

Most QMS are not designed to handle the increased complexity coming with the IVDR, especially for communication with *external stakeholders*

NEWBIES:
ISO Certification Audits are the hardest audit type in the regulated world outside of for cause audits

BE KIND TO YOUR AUDITOR

FDA ≠ ISO

Pop Quiz!

How many economic operators does your company have for EU?

What regulated activities do they perform for you?

Do you have objective data to support your position on your relationship with them?

Go visit your Key Economic Operators. Don’t let your Notified Body get there first

A world of hidden horrors is waiting for you

Let’s do some quick HR Maths

Assumption

Humans review your file, not AI bots

\+ Market Inversion

\+ Fewer Notified Bodies, limited scopes

\+ NBs are profit-driven orgs

=

Business Selection

File Reviewability

Human Factors

Delays

Nothing New Under the Sun

UDI

Not New to industry but maybe new to you

Takes a very long time to implement

RAQP / MDQP

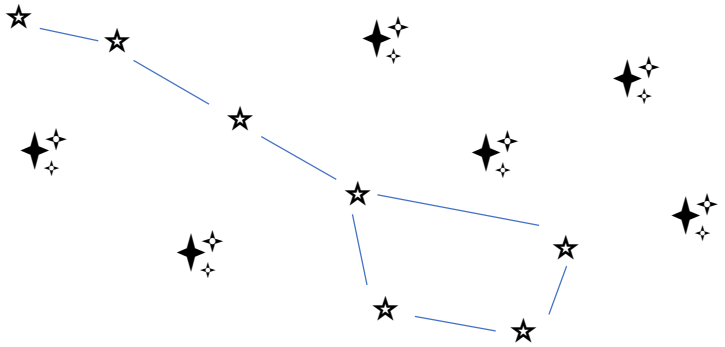
The idea has existed in Pharma for ages

Execution may be bumpy at first as we figure out what this should look like

RISK

Risk officially lives in the TF once approved

You have to show its alive and well in all systems

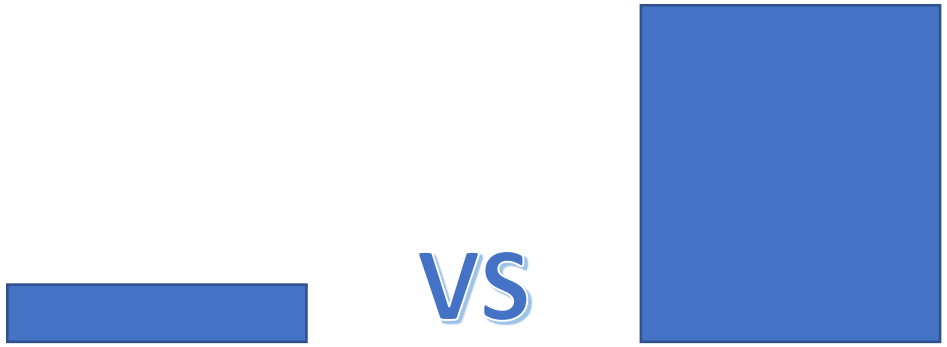


Commit resources to active reading and analysis

Assign Teams. Use both section and topic-based reading assignments

Group think afterwards to see if you found everything

The IVDR is poorly organised



The Canada Question

Do we stay or do we go now?

YES

- Gap assessment
- Clinical investigations
- Nice up the TF
- UDI
- New contracts with external stakeholders
- Update QMS
- Appoint RAQP

NO

- Market Withdrawal
- Notice to external stakeholders
- Update QMS

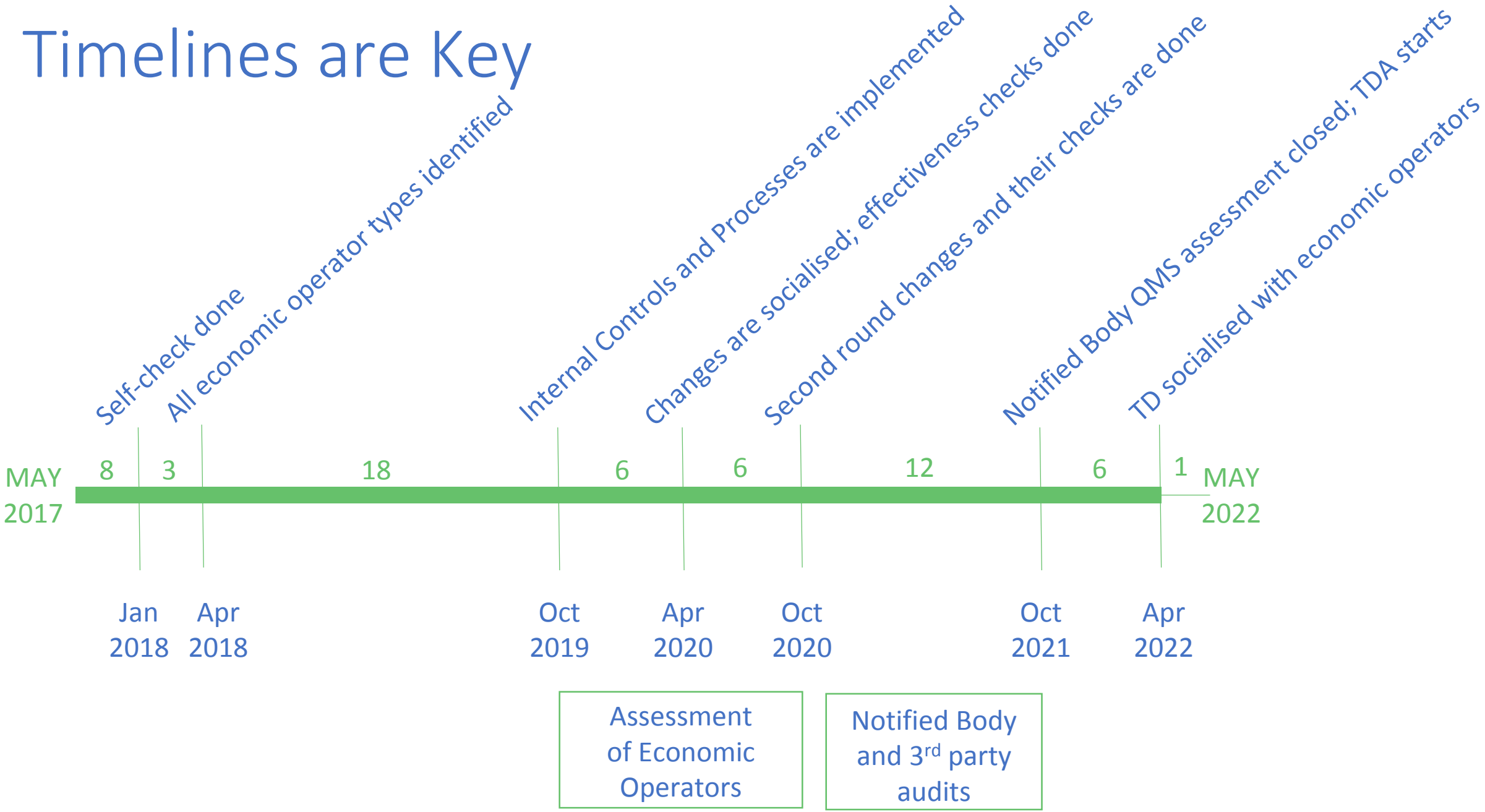
MAYBE

- Gap assessment
- Clinical investigations
- UDI
- New contracts with external stakeholders
- Update QMS with bare minimum

NULL

- Market Withdrawal
- Notice to external stakeholders
- Update QMS

Timelines are Key




Any Questions?
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Thank You for Your Time

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