

Left & Right Brain Thinking

Read out the color not the word

Yellow

Blue

Orange

Black

Red

Green

Purple

Yellow

Red

Orange

Green

Black

Blue

Red

Purple

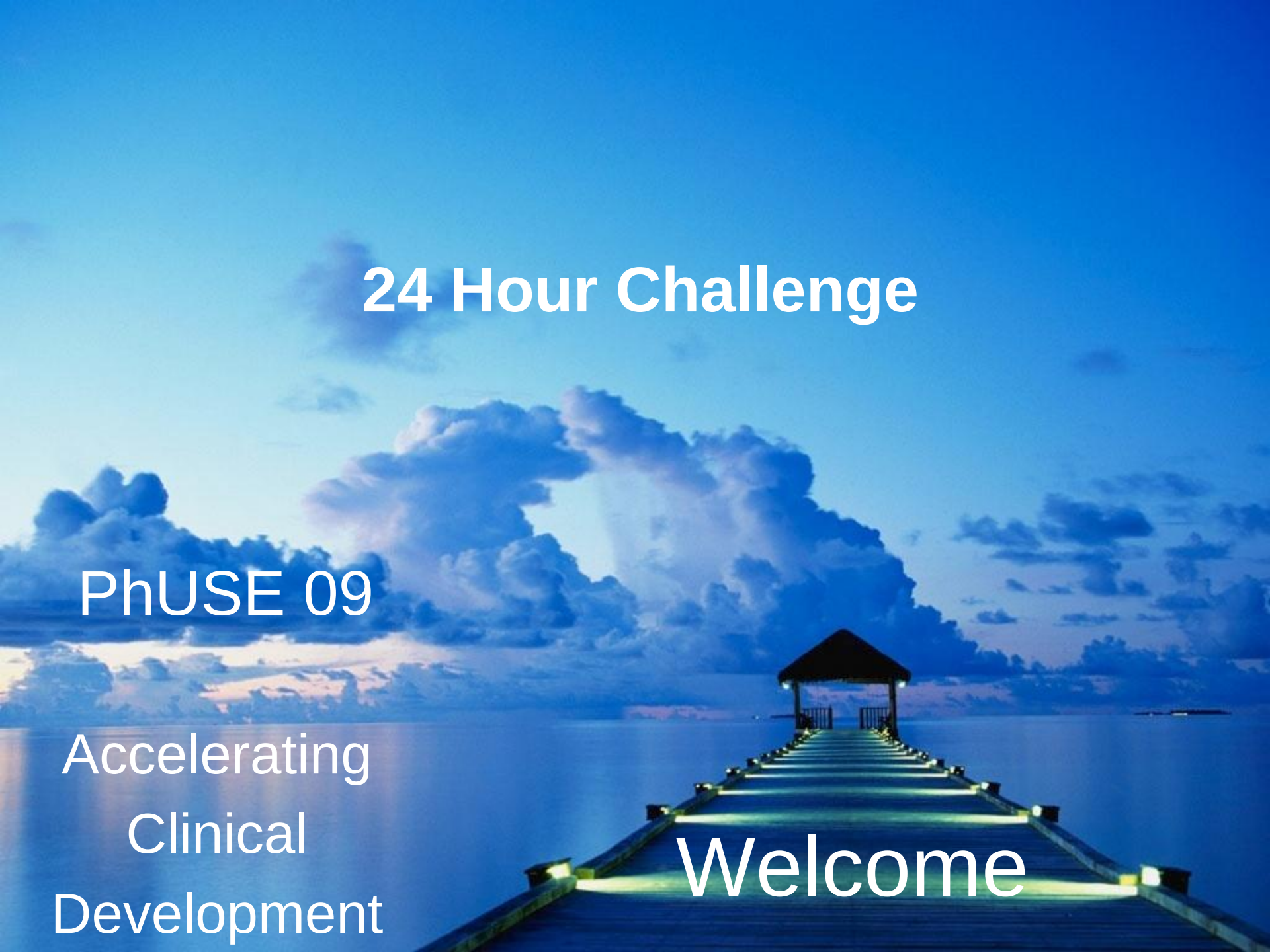


24 Hour Challenge

PhUSE 09

Accelerating
Clinical
Development

Welcome



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 - Business Analyst – AstraZeneca Pharmaceuticals



24 Hour Challenge Overview

- Optimising the way AstraZeneca responds to regulatory requests
- Regulatory Knowledge and Information
 - Submission to Regulatory Authorities
 - Defence of product information
- '24' Hours is an aspirational target



24 Hour Challenge Overview

- Outlining the problems – root cause analysis
- Knowing how information flows
 - Within and across functions
- Gain a true understanding of the information that supports the label –
 - Data
 - Information
 - Knowledge
 - Wisdom
- Measure and improve the speed and accuracy of how it can be accessed



Create, Store, Retrieve

- Building awareness

“How we create and store information today will achieve effective retrieval in the future”

“Traceability back to the raw data needs to be done in an efficient and effective timeframe”



24 Hour Challenge

- The focus is on
 - Governance
 - Behaviours
 - Audit/Metrics
 - Stakeholder Management
 - Process

Good Information Management

This is not a technology response although the end point may need to have technology element



Governance

- Governance is key to delivering the change required
- This spans across R&D and operations
- This has meant sponsorship from a Senior Executive Team level
- The changing landscape of the industry means that we need to maintain our focus on the traceability of regulatory knowledge and information

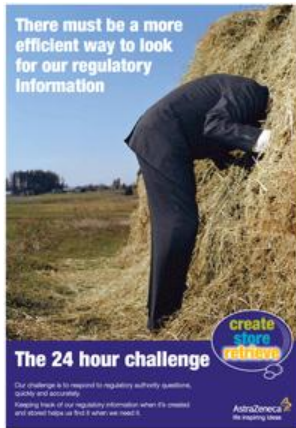


Governance

- Compliance to policy relating to Regulatory Knowledge
- Day to day adherence to definitions
- Understanding of internal and external drivers
- Tactical responses
- Strategic Roadmap to deliver towards vision



Communication and Behaviours



- Behavioural changes across a large organisation can be daunting
- Communication plan has focused every individual
 - SET
 - Leadership teams
 - Functional Areas
 - Individuals

Communication and Behaviours



- Message around the effective creation storage and retrieval of our products throughout it's lifecycle
- Posters
- Training and awareness sessions
- Videos
- Portal
- Newsletters

Audit and Metrics

- Already have many projects focussed on improving the submission of a product
- There is also a focus here on the approval and lifecycle of a product
- To gain and measure success:
 - Mapping out our current information flows
 - Looking at root cause problems
 - Providing a vision as to where we want to be
 - Build in Measures
 - Audit our compliance to policy
 - Put in controls



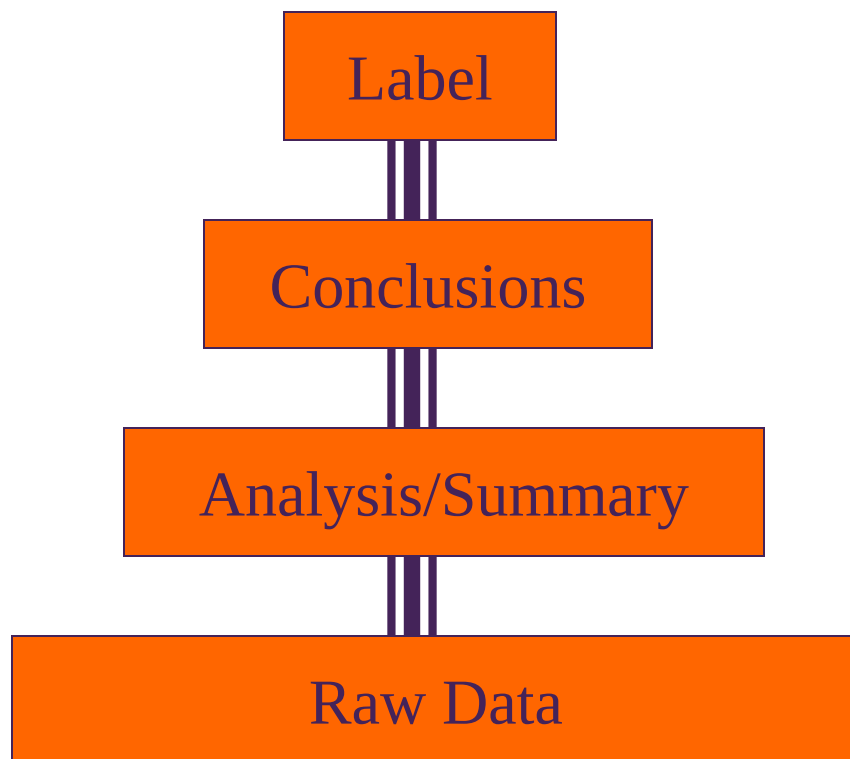
Stakeholder Management & Buy-in

- Everyone in R&D and operations is a stakeholder
- Establish decision makers and blockers
- Continuously manage stakeholders
- Buy-in needs to be documented and communicated



Information Principles

- “Information is information”
- Data, Information, Knowledge used interchangeably



Information Principles

- Should be more information focussed not document focussed
- This will allow better traceability back to the raw data from any summary or conclusion
- Need to support statements in label:
 1. Safety
 2. Efficacy
 3. Quality
 4. Patient Population



Conclusions

- To be more effective in management regulatory knowledge and information
 - Governance
 - Behaviours
 - Information Maturity
 - Traceability of data, information, knowledge and wisdom
- Our ultimate measure to success is to have no questions back from the authorities
 - High quality of information supporting the label
 - Faster approval



24 Hour Challenge

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Thankyou

Ice-Breaker Catch Phrase

rlalldlilnlg

1

The Left Dark

Uckly

Lkylu

Lucky

No No
No Punch No
No No No

ECNALG

STAND

I