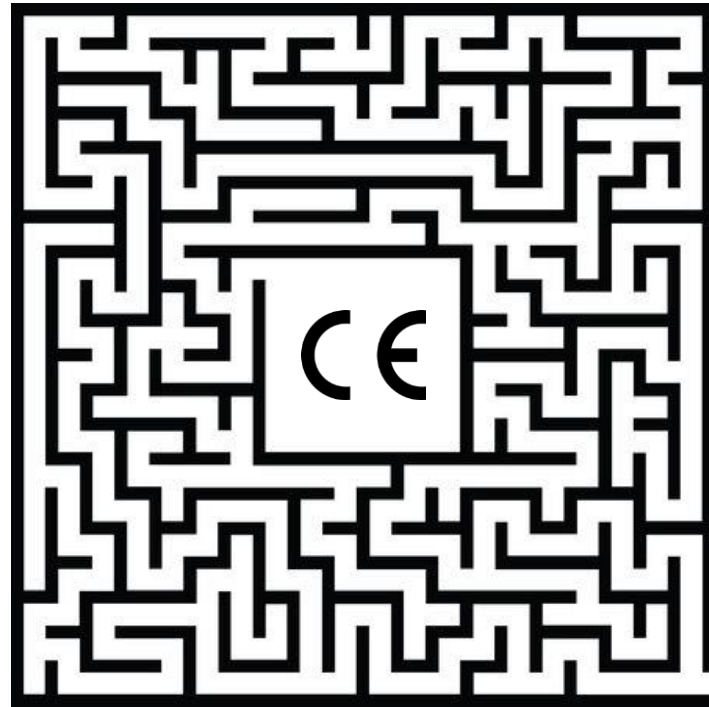# aligned

Are we there yet?

Using KPIs to track Technical File progression

Setting the stage

- Development of our Medical Device is underway

- Involves a lot of people

- Producing a lot of (interdependent) documents

- Everything needs to be "ready" at release date

The Questions

- How do we know where we are?

- What work remains until we can release?

- Can we close the gaps in time?

Measuring the way home

- KPI = Key Performance Indicator

- Evaluates success of an activity

- Single metric – easy to understand

- Actionable!

- Examples:

  - Average percentage of booked seats (Airlines)

  - Average length of stay (Hotels)

  - Average customer waiting time (Restaurant)
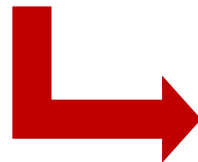
The theory of KPI's

- Articulate the Goals / Objectives
  - Profit
  - Number of Votes
  - Winning Champions League
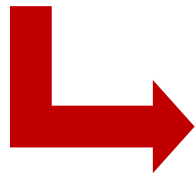
- Critical Success Factors
  - Customer retention
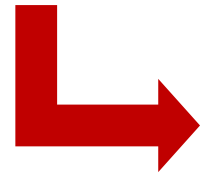 - Reach voters with message
  - Score Goals

- Performance Metric
  - Repeat purchase ratio
  - Share of voice
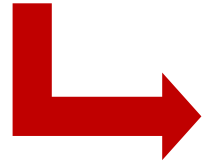 - % time spent attacking

KPI's for Technical File progression

- Goal: Compliant Technical File

  - Critical Success Factors

    - Complete
    - Correct
    - Consistent

    - Performance Metrics

      - Document Metrics
      - Content Metrics

Document Measurements

- Do we have the right documents?

- Are they up to date?

- Have they been reviewed?

- Have they been released?

Examples from Aligned Elements

aligned

MISSING DHF DOCUMENTS

2

DOCS TO CREATE

OUTDATED DOCUMENTS

24

DOCS WITH STALE DATA

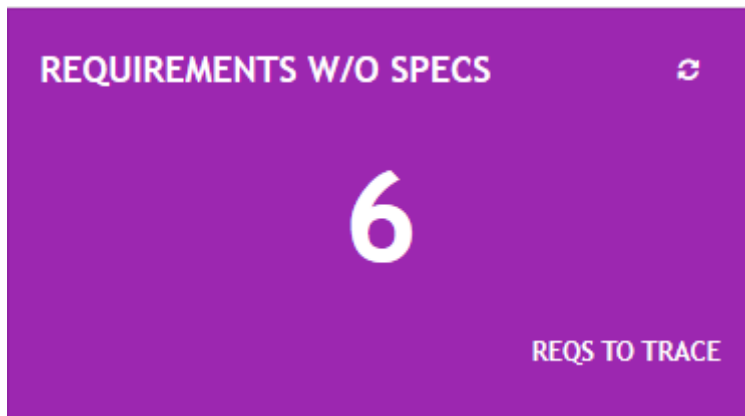DOCUMENT REVIEW STATUS
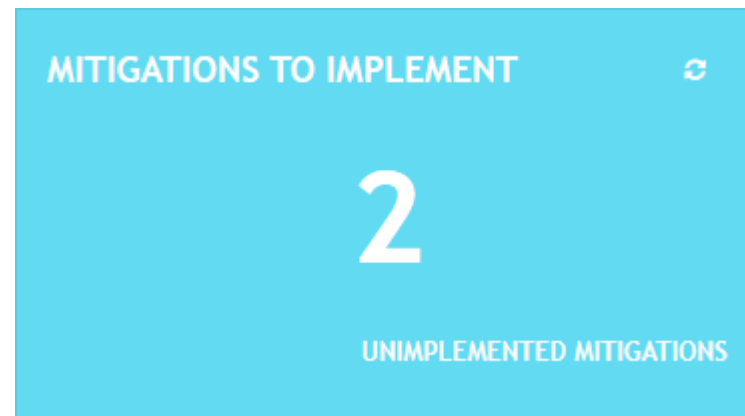
2

DOCS TO REVIEW

OPEN SIGNINGS

6

DOCUMENTS TO SIGN

Document Content Metrics

- Requirement Management

- Risk Management

- Test Management

Example: Requirement Management

EMPTY FIELDS IN REQUIREMENTS

2

REQS TO COMPLETE

REQUIREMENTS MARKED #TBD

2

REQS TO FINALIZE

REQUIREMENTS W/O SPECS

6

REQS TO TRACE

ORPHANED REQUIREMENTS

24

REQS WITHOUT USER NEED

Example: Risk Management

UNASSESSED POTENTIAL HAZARDS

2

HAZARDS TO ASSESS

EVALUATION INCOMPLETE

24

RISKS TO EVALUATE

INSUFFICIENTLY MITIGATED RISKS

6

RISKS TO MITIGATE

MITIGATIONS TO IMPLEMENT

2

UNIMPLEMENTED MITIGATIONS

Example: Test Management
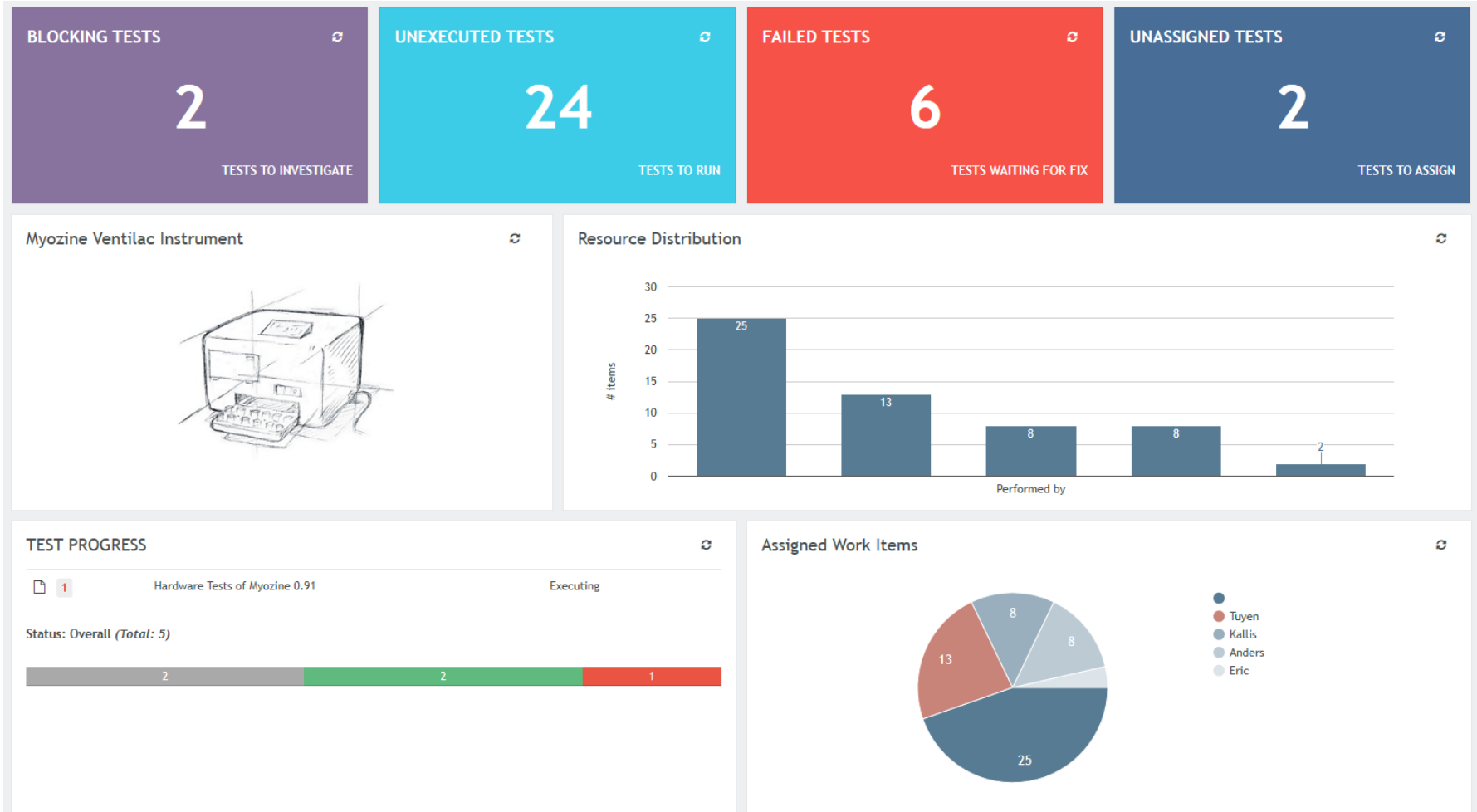
Observations

- Document progress does not tell the whole truth

- Different users have different needs

- Metrics shall provide insight and be actionable

Which metrics are best for me?

- Metrics aligned with your goals

- Metrics based on timely available data

- Metrics based on cheaply collected data

- Metrics that are supported by your the team

Aligned Elements – a medical device ALM

- Manage your Technical Documentation

- Version Control + Traceability + Documents

- Integrated Risk Management

- Integrated DHF Index

- Reviews + Workflows + E-signatures

- Automatically finds formal gaps and errors

- Ensures completeness and consistency

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Thank You!