Key considerations for sourcing and managing data handling services, processes and systems in oncology trials

Anders Mortin, TriTiCon

CLINICAL OPERATIONS IN ONCOLOGY TRIALS EUROPE 2019

ZÜRICH, NOVEMBER 2019

Clinical Operations in Oncology Trials

WHAT DO YOU

NEED

TO MAKE INFORMED DECISIONS ?

DISCLAIMER

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Key characteristics for data collection & handling in Oncology trials

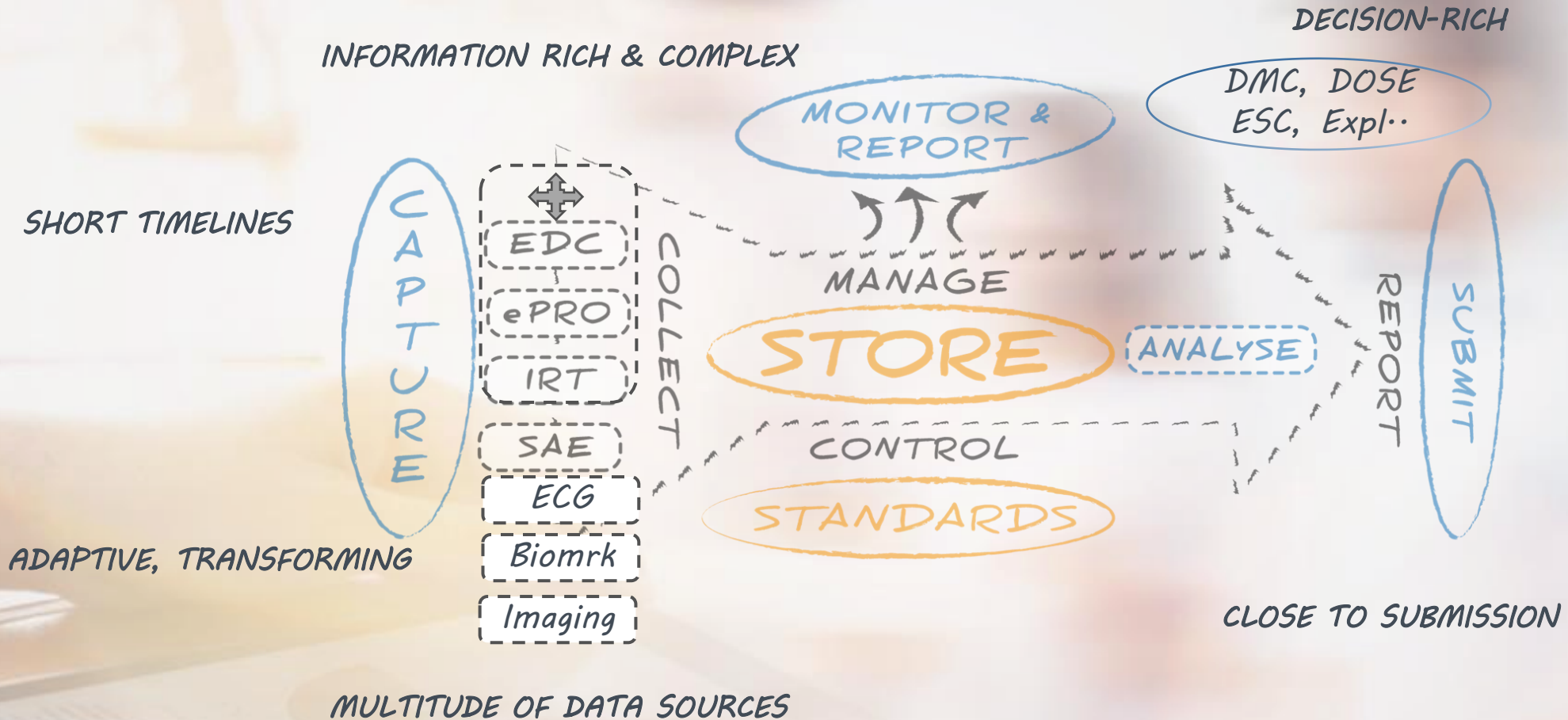Requirements & considerations for biometrics services & systems

10 things to look out for in the trial technology space

Summary & questions

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Key characteristics
- Data collection & handling in oncology trials

INFORMATION RICH & COMPLEX

DECISION-RICH

SHORT TIMELINES

ADAPTIVE, TRANSFORMING

MULTITUDE OF DATA SOURCES

CLOSE TO SUBMISSION

CAPTURE

COLLECT

EDC
ePRO
IRT
SAE
ECG
Biomrk
Imaging

MONITOR & REPORT

MANAGE

STORE

ANALYSE

CONTROL

STANDARDS

REPORT

SUBMIT

DMC, DOSE ESC, Expl··

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Trial characteristics and *biometrics service requirements*

CHARACTERISTICS

- Short start-up times
- High number of collection systems/sources/vendors
- Information rich and complex CRFs
- Adaptive, transforming trial designs
- Decision-rich (Dose escalations, DMC, business decisions,).
- Short path to submission

&

SERVICE REQUIREMENTS

- Strong PM and oversight
- Start early, work in parallel
- Oncology understanding
- Flexible and dynamic (people and processes)
- Strong Technical skills and IT backbone
- Day 1 & continuous delivery capability

DEFAULT SERVICE IS NOT ENOUGH – ENSURE ALIGNED EXPECTATIONS

Trial characteristics and *operational considerations*

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OPERATIONAL CONSIDERATIONS

- Number of vendors
- Capacity
- Geographical coverage
- Independency, flexibility
- Company match
- Costs

WHAT IS MOST IMPORTANT FOR *YOU* ?

Vendor categories vs. vendor characteristics - generalized

VENDOR CATEGORIES	VENDOR CHARACTERISTICS	
	BIOMETRICS	**OPERATIONAL**
› BIOMETRICS FSP	Custom, seamless	Other functions are on you
› BIOMETRICS ONCOLOGY VENDORS	Specialized	Risk for limited capacity
› BIOMETRICS VENDORS	Focused, but not specialized	Risk for oncology gaps
› ONCOLOGY FULL SERVICES CROS	Often operational core	Risk for service gaps
› (LARGE) FULL SERVICE CROs	Generic Service	End2end delivery

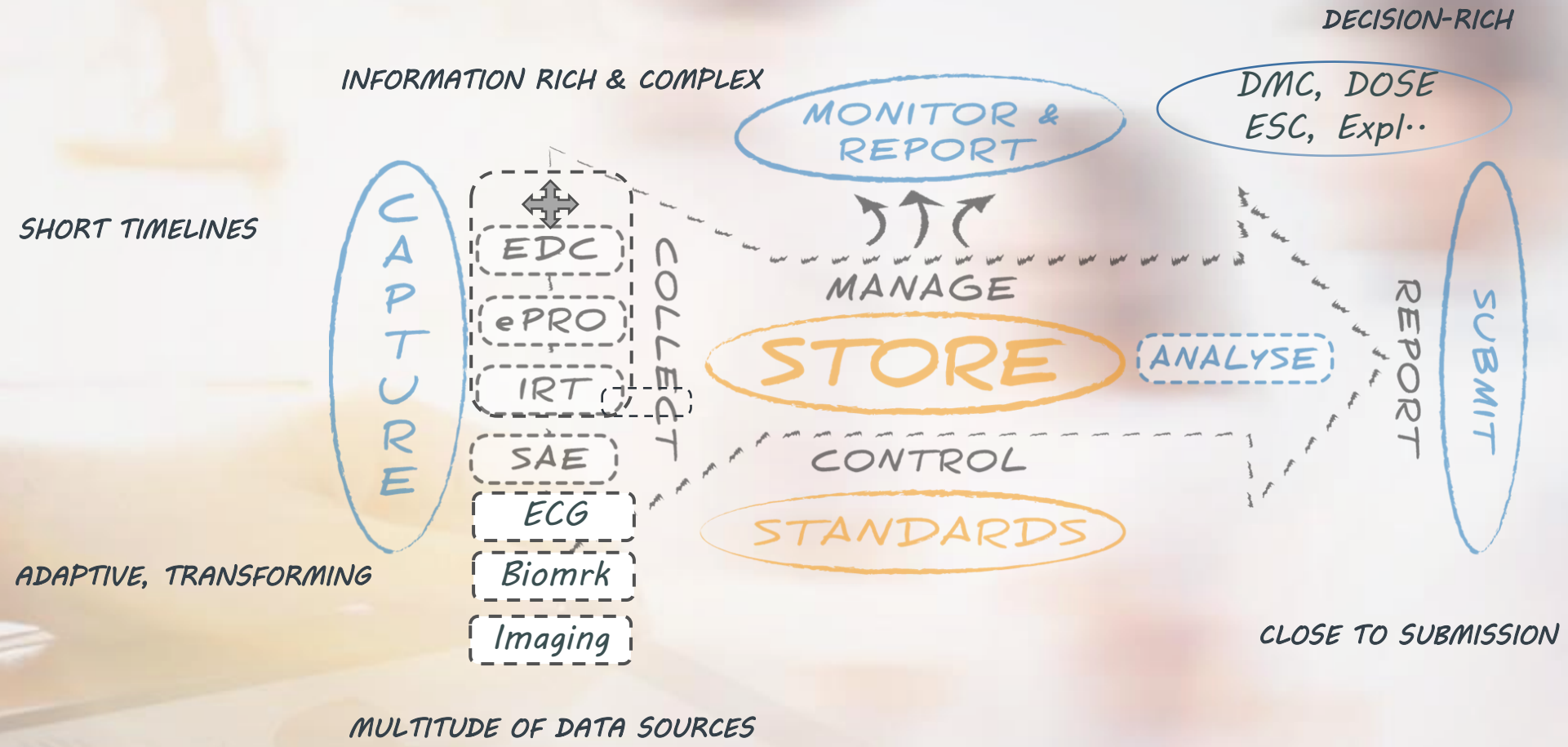TriTiCon

Sourcing models - biometrics fit

BIOMETRICS FIT

H

BIOMETRICS FSP

BIOMETRICS ONCOLOGY VENDORS

BIOMETRICS VENDORS

ONCOLOGY FULL SERVICES CROS

(LARGE) FULL SERVICE CROS

L

H

OPERATIONAL FIT

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Sourcing models - biometrics and operational fit

BIOMETRICS FIT

H

L

SPONSOR

BIOMETRICS FSP

BIOMETRICS ONCOLOGY VENDORS

BIOMETRICS VENDORS

ONCOLOGY FULL SERVICES CROS

(LARGE) FULL SERVICE CROS

SPONSOR

CHOOSE & BALANCE WITH YOU AND OTHER PLAYERS…

H

OPERATIONAL FIT

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Requirements & considerations for *biometrics systems*

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INFORMATION RICH & COMPLEX

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CLOSE TO SUBMISSION

MULTITUDE OF DATA SOURCES

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Trial Characteristics and system requirements
- Data collection & handling in oncology trials

CHARACTERISTICS

- Short start-up times
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SYSTEM REQUIREMENTS

- Simplify data flow, minimize dependencies
- Ensure system capabilities (functionality)
- Day 1 data availability.
- Continuous and multi-purpose reporting capabilities.
- CDISC & submission ready from start
- Capabilities for changes

IT TAKES A LITTLE BIT MORE – THE DEVIL IS IN THE DETAILS!

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Trial Characteristics and system requirements
- Top 4 must haves

SYSTEMS WITH REQUIRED TECHNICAL CAPABILITIES

(A LITTLE BIT OF) KEY KNOWLEDGE

DATA – AND DOCUMENTATION- IN CDISC FORMAT

GET YOUR DATA – OFTEN. STORE IT SAFE

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10 things to look out for in the trial technology space.

1. Challenge and dare – you can (and must)

OLD "TRUTHS" ARE NOT VALID ANYMORE

NEW REQUIREMENTS, NEW OPPORTUNITIES

NEW SYSTEMS, NEW TECHNOLOGY BETTER THAN EVER

DARE TO BE DIFFERENT - GET IT YOUR OWN WAY!

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2. Flow is up, integration is down

**MAKE YOUR DATA AVAILABLE!
FROM DAY 1
AUTOMATED
CONTINUOUS
....AND META DATA**

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3. Use the data - consolidate and BI

MAKE YOUR DATA WORK FOR YOU!

ACTION • DATA • INFORMATION • KNOWLEDGE

OPPORTUNITY & REQUIREMENT

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4. EDC – Go big or go ~~home~~ small

= System

YESTERDAY → TODAY

MARKET SHARE

L

S

L   SYSTEM SCOPE

SYSTEM FOOTPRINT

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4. EDC – Go big or go ~~home~~ small

MARKET SHARE

L

YESTERDAY → TODAY

= System

CHOOSE BASED ON YOUR OWN NEEDS

S

L SYSTEM SCOPE

SYSTEM FOOTPRINT

The 3 Tiers Consulting Company

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5. ePRO – Time is changing

TECHNOLOGY

G

TIMELINES

L

G

SERVICE

H

COST
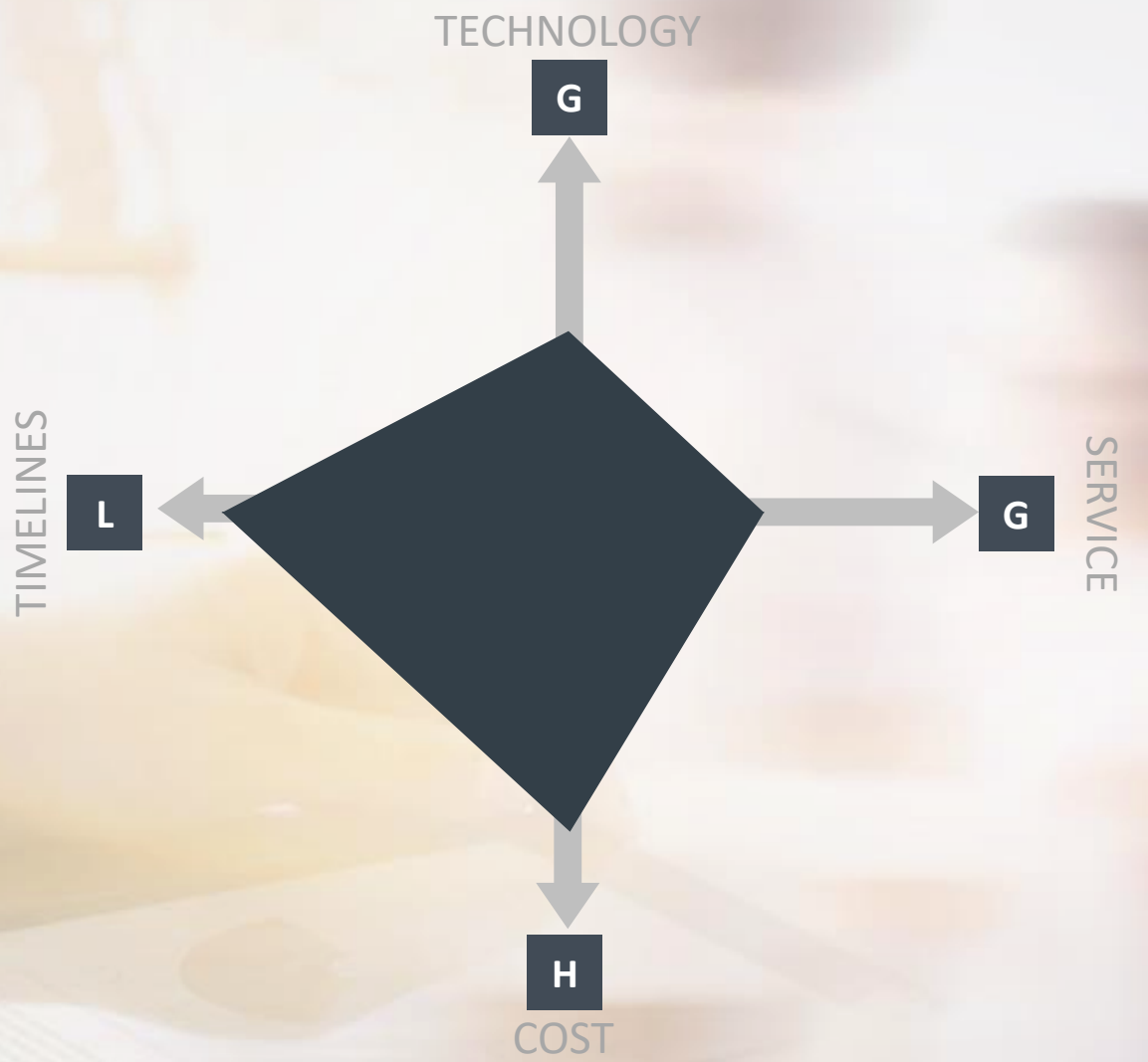
CURRENT LEADERS - TIME FOR SOMETHING NEW?

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5. ePRO – Time is changing

TECHNOLOGY

G

TIMELINES

L

G

SERVICE

H

COST
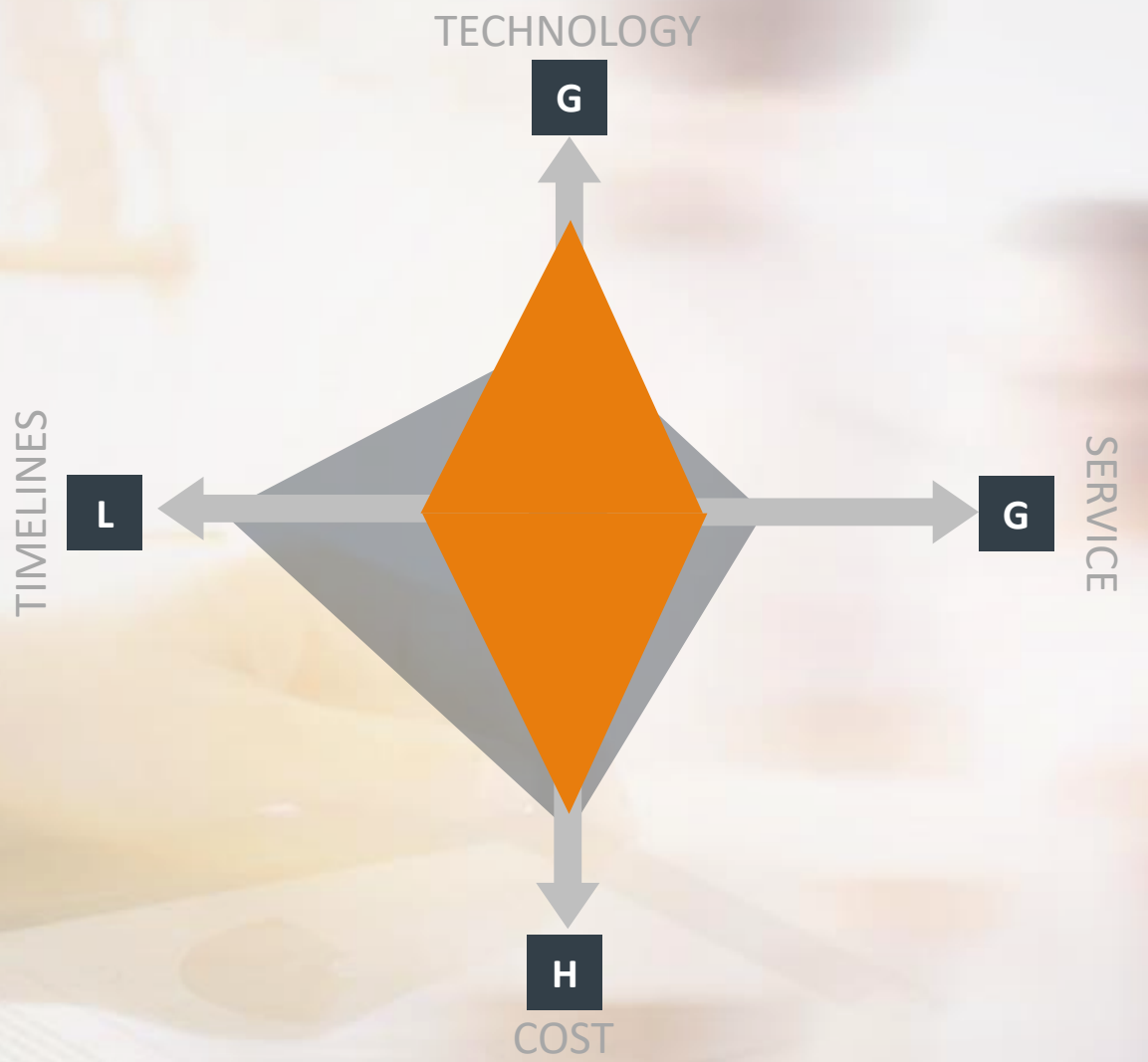
NEW KIDS ON THE BLOCK – TIME FOR A CHANGE ?

System Scope

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5. ePRO – Time is changing

TECHNOLOGY

G

TIMELINES

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SERVICE

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COST

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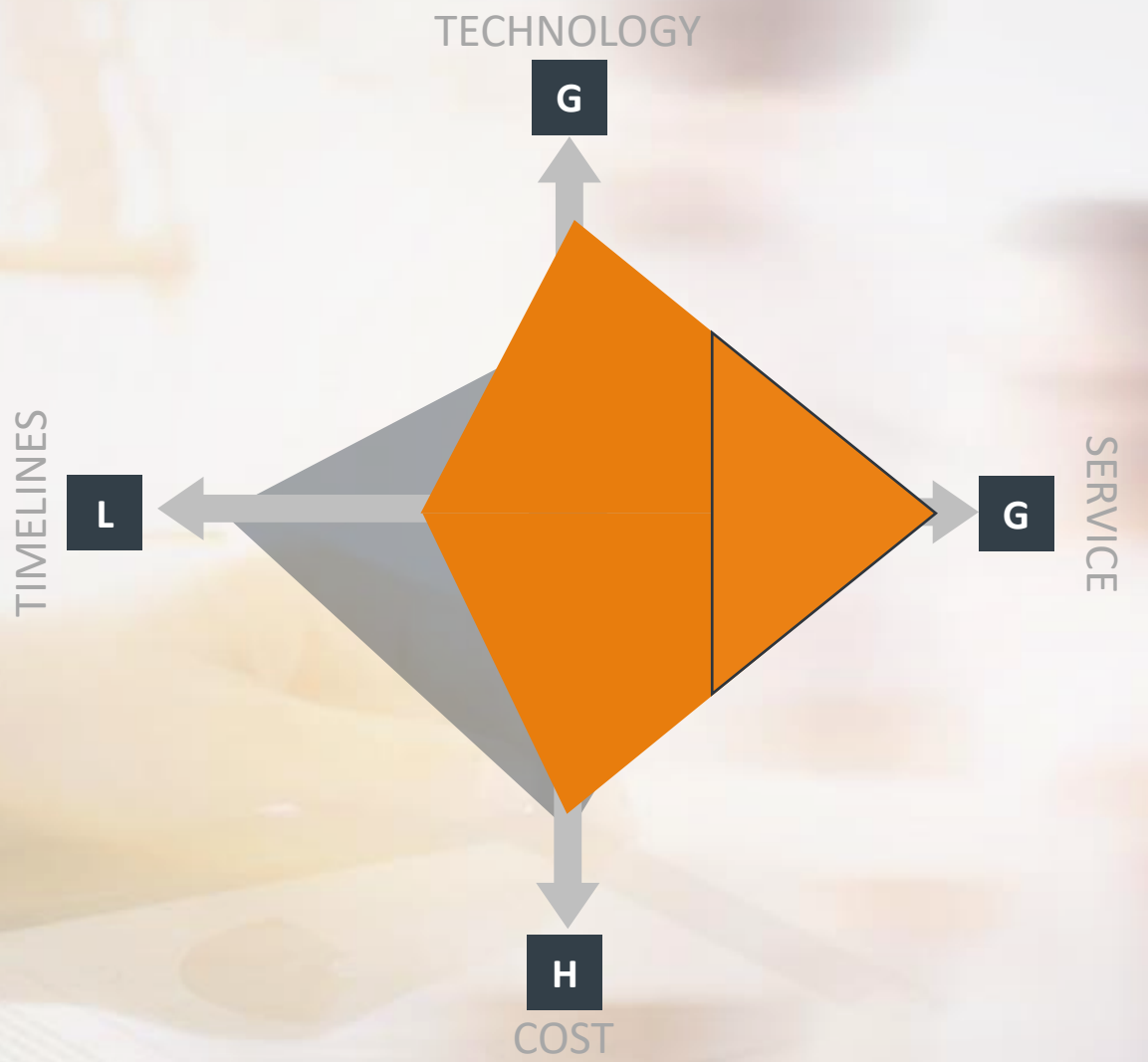
**NEW KIDS ON THE BLOCK
– NEW COMBINATIONS?**

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5. ePRO – Time is changing

TECHNOLOGY

G

TIMELINES

L

SERVICE

G

COST

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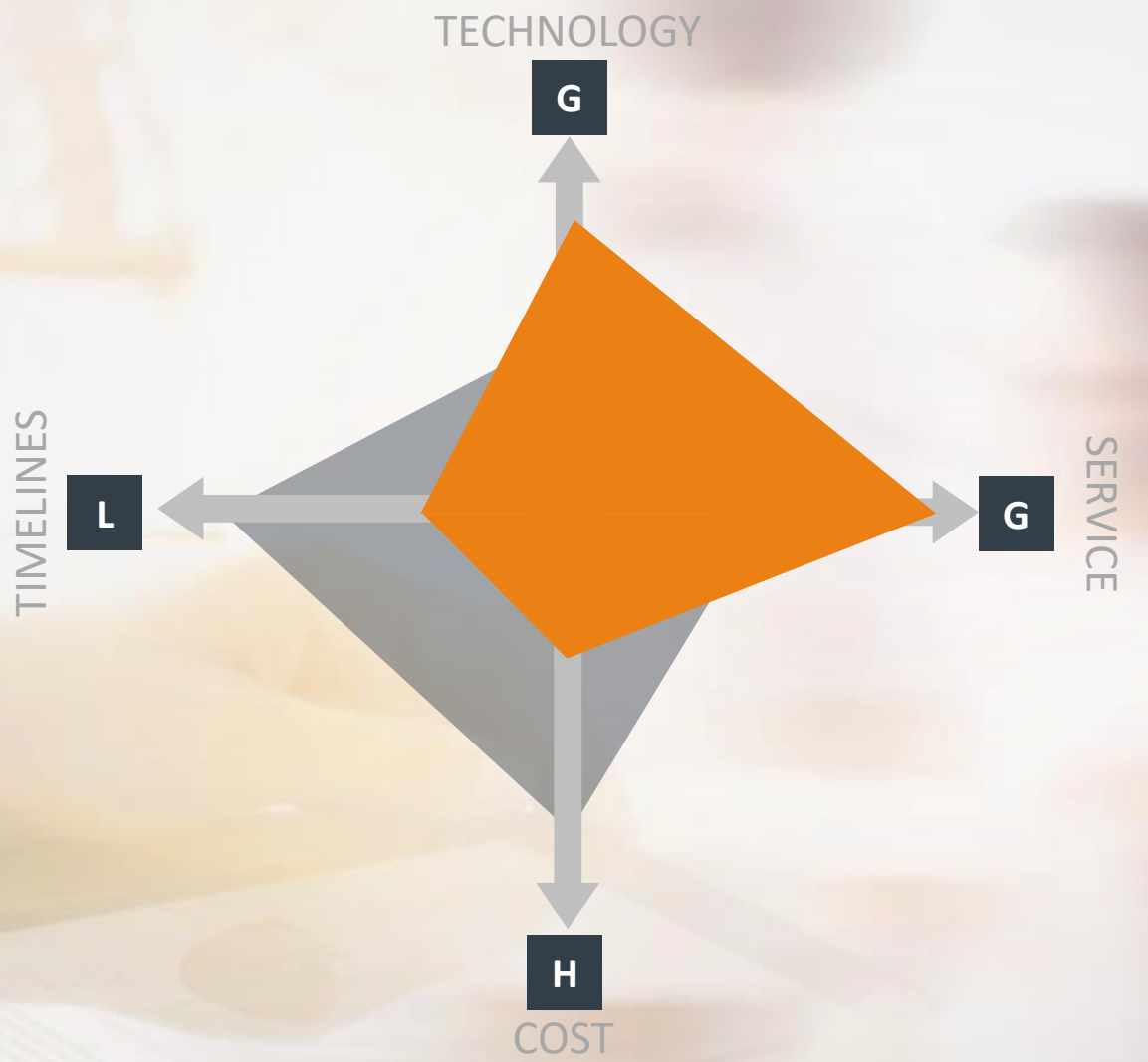
- **TECHNOLOGY BY EDC PROVIDER S**
- **NEW TECHNOLOGY PROVIDERS**
- **SERVICES BY CRO OR TRANSLATION VENDOR**
- **NEW APPROACHES TO PRE-MADE LIBRARIES**
- **VALIDITY AND VALIDATION → COMMODITY**
- **DEVICE LOGISTICS → OBSOLETE**
- **CONNECTIVITY → GIVEN**

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6. Big data, AI, virtual – it is here

BIG DATA, AI & VIRTUAL

- ✔ *SoMe, patient driven trials and platforms*

- ✔ *Virtual trials, registry trials*

- ✔ *Site performance forecasts, Protocol design BI*

- ✔ *AI*
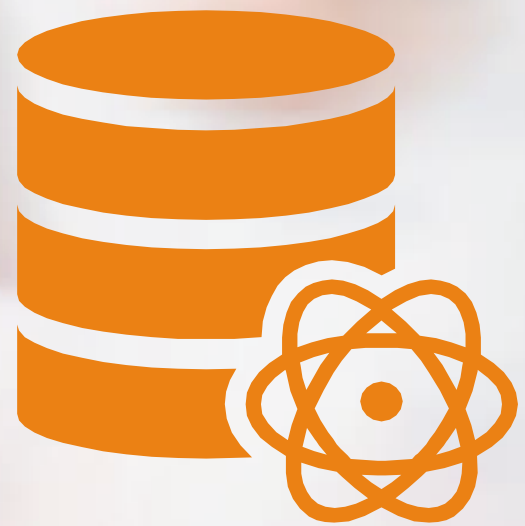
**IT'S REAL - NOW
IS THERE AN OPPORTUNITY OR A SOLUTION FOR YOU ?**

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7. Standards - for real, for everything

HARVEST THE BENEFITS – BE COMPLIANT

- ✓ *Ready made*
- ✓ *Best practice*
- ✓ *Required*
- ✓ *Enhancing value*
- ✓ *Flexible*

&

ACROSS THE BOARD

- ✓ *CRFs*
- ✓ *Data and Reporting*
- ✓ *Safety updates*
- ✓ *Trial registries*
- ✓ *eTMF*
- ✓ *Submission*

ITS AN ENABLER – NOT A CONSTRAINT

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8. Mind the sites (...and yes patients as well)

OF SYSTEMS

OF INFORMATION CHANNELS

OF CHANGES

SITES ARE THE USERS, IS THE SET-UP MADE FOR THEM ?

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DO YOU HAVE THE USER IN FOCUS – FOR REAL?

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9. Validation, legislation and documentation – Get it right!

VALIDATION, LEGISLATION & DOCUMENTATION

- ✓ *More requirements*

- ✓ *More legislation*

- ✓ *Increased regulatory focus*

DON'T RISK IT!

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10. Techknowlodgy

TECHKNOWLODGY

- It is here, its there it is everywhere.

- It is not rocket-science, but it is a lot of small things you need to know.

- You need a little bit of key knowledge to deal with it.

- Get it right!

YOU DON'T NEED IT ALL – BUT YOU NEED IT RIGHT

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10 things to look out for in the trial technology space

1

CHALLENGE AND DARE – YES YOU CAN!

2

FLOW IS UP, INTEGRATION IS DOWN

3

USE THE DATA - CONSOLIDATE AND BI

4

EDC – GO BIG OR GO ~~HOME~~ SMALL

5

ePRO – TIME IS CHANGING

6

BIG DATA, AI, VIRTUAL – IT IS NOT COMING, IT IS HERE

7

STANDARDS -FOR REAL, FOR EVERYTHING

8

MIND THE SITES (...AND YES PATIENTS AS WELL)

9

VALIDATION AND DOCUMENTATION – GET IT RIGHT!

TECHKNOWLODGY

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Summary

WHAT TO ENSURE

- ✓ Balance your vendor strategy
- ✓ System capabilities
- ✓ CDISC your data & Keep it safe
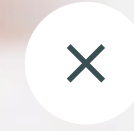- ✓ Technowledge to manage

WHAT TO BE AWARE OF

- ✗ Default service is not enough
- ✗ You are different
- ✗ Mind the site
- ✗ Get it right!

TRIALS ARE TRANSIENT – DATA IS FOREVER

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THANK YOU & QUESTIONS

Anders Mortin, TriTiCon ApS

Combined Skills and Experience to Meet Your Challenge

eClinical Consultants and Experts in Clinical Data Processes and Systems. From strategy to end-user training, the TriTiCon team is ready to help you all the way in establishing your end-to-end solution for handling of clinical data.

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The Company – The 3 Tiers Methodology
- Meeting Your Challenge

Strategic Understanding

Understanding and adopting to your company

Project Management

Right methodology for each situation

Subject Matter Knowledge

Knowing the solutions

WHAT YOU NEED – NOTHING MORE, NOTHING LESS

Subject Matter Expertise is at the core of all our services. No process or system will work well if the details are not right

Large program, critical projects or key tasks, we adjust our project management methodology and tools to meet the needs of the specific situation.

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