WEBINAR

Employing Strategies for Effective Risk and Capability Assessments When Choosing a Clinical Vendor

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Vice President of Operations
THE AVOCA GROUP

February 21, 2018

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exl events

Topics

1. Strategies for effective risk and capability assessments when choosing a clinical vendor
2. Determining critical factors to take into consideration
3. Effective assessment tools and processes for qualification
4. The value of centralized resources for qualification information and assessment

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Pharma Industry Focus:
Clinical Research/Clinical Outsourcing

ICH E6 (R2)

Revisions to ICH have created an impetus for evaluating Provider oversight processes and documentation, inclusive of provider qualification, and selection.

5.2.2 Addendum

The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, **including trial-related duties and functions that are subcontracted to another party by the sponsor's contracted CRO(s).**

What Actions Are Being Taken to Address ICH E6 (R2)?

Focus on Risk Management

"We are adding a more holistic approach to risk management to our overall trial management processes. This is a big world view change for our organization and will take some time to implement both on paper and in the minds of our staff."

Aligning/Formalizing Processes & Tools

"Introduction of new risk management SOP and associated templates, updates of other numerous SOPs which are impacted by this approach."

Training

"Train clinical teams to understand risk assessment approaches for proactively reducing risk."

Focus on Oversight

"Moving to RBM and more fully embracing a risk-based approach to managing trials and vendors, and also insisting that CRO partners use this approach also."

Implementing/ Improving QMS

"We are creating an Integrated Quality Management Plan for the company that will formalize many of the risk management processes that we currently perform in a more informal fashion. Additionally, we have created a clinical Quality Management Council that will be able to review risks and issues in an ongoing manner."

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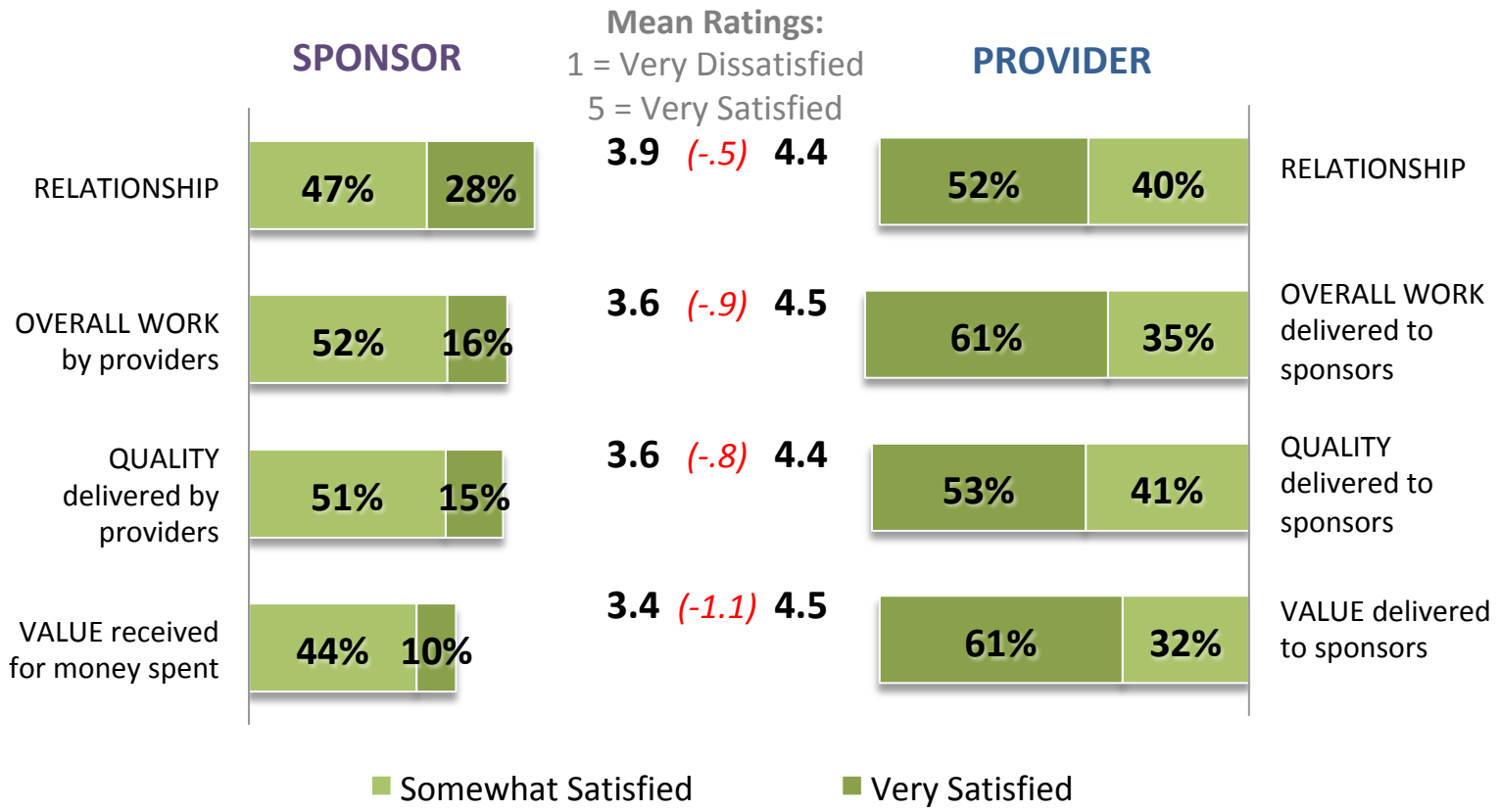
Why Qualify Service Providers?

Overall Assessment of Relationship Health: Sponsors vs. Providers



N: SPONSOR=255-265; PROVIDER=117-120

Q: Thinking about your experiences in 2016, how satisfied are you with…

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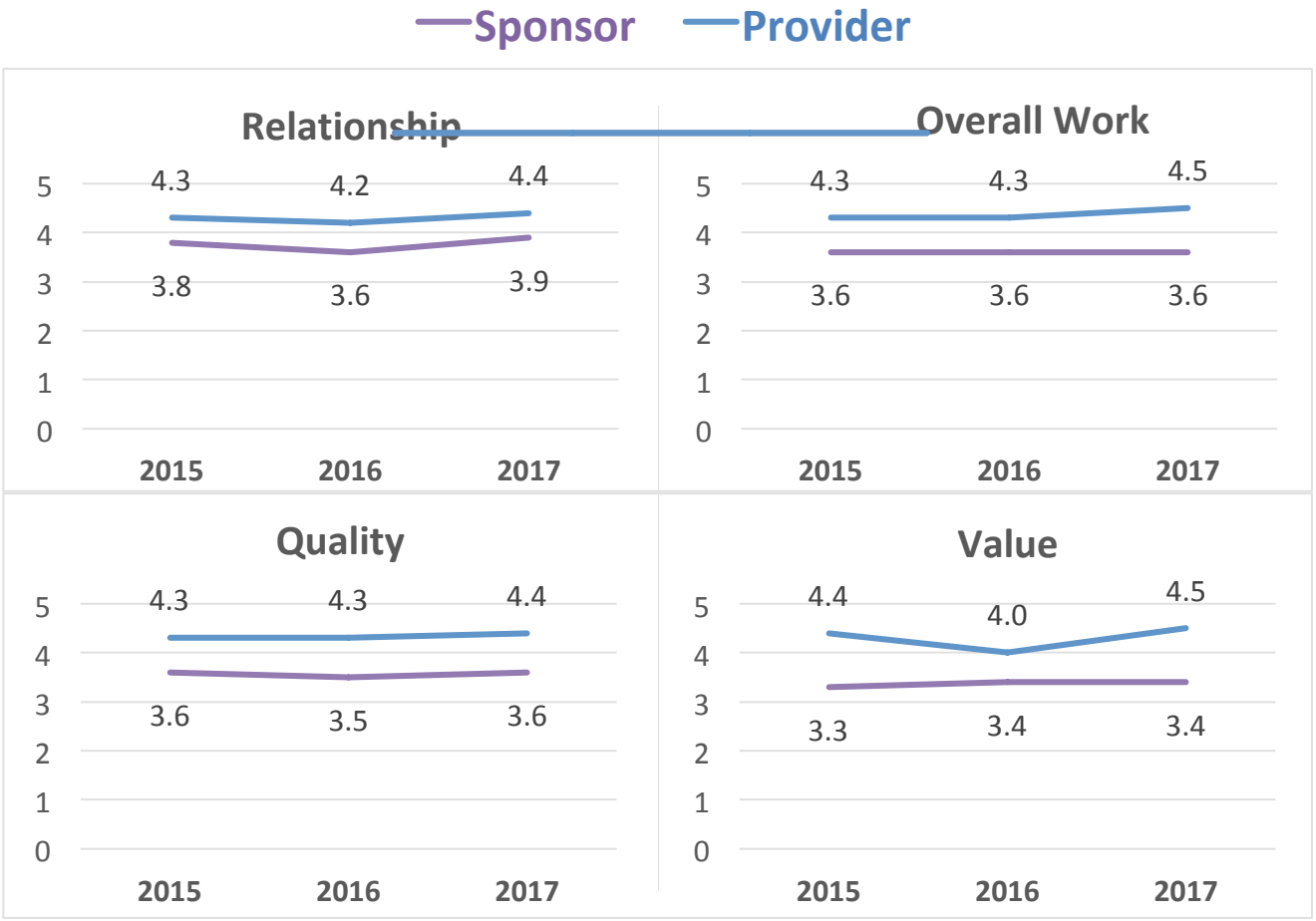
Why Qualify Service Providers?

Trend in Overall Assessment of Relationship Health



2015 N: SPONSOR=148-152, PROVIDER=88-90; 2016 N: SPONSOR=104-105, PROVIDER=56-60; 2017 N: SPONSOR=255-265; PROVIDER=117-120

Q: Thinking about your experiences in 2016, how satisfied are you with…

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Strategies for Effective Risk & Capability Assessments

Define Requirements

Plan your vendor qualification strategy considering internal and external factors.

"If you know the enemy and know yourself, you need not fear the result of a hundred battles. If you know yourself but not the enemy, for every victory gained you will also suffer a defeat. If you know neither the enemy nor yourself, you will succumb in every battle."

— **Sun Tzu**, **The Art of War**

Define Requirements in Category

Internal Analysis and Planning: The process by which desired capabilities, operational requirements, and the sourcing strategy are defined.

- **What services/capabilities are desired?**
  - Stakeholder analysis and engagement
- **What are the organizations requirements?**
  - Compliance with procurement, legal, financial, quality requirements
- **How do we want to approach the umbrella category and its sub-parts?**
  - Alignment to the overarching sourcing strategy

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Define Requirements in Category

Internal Analysis and Planning: The process by which desired capabilities, operational requirements, and the sourcing strategy are defined.

- Regulatory
- Assurance of Supply / Sustainability
- Quality
- Service
- Cost
- Innovation

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Define Requirements in Category

External Analysis and Planning: The process by which we explore the market for capabilities and providers within the category, including emerging and future trends (threats and opportunities).

- **Who and what is in the market?**
  - Who: Providers
  - What: Products/Services
- **What is happening and what is changing?**
  - Business Landscape – Consolidation? Expansion? Fragmentation?
    - Who are the providers?
    - Who are entrenched and who are new entrants?
  - Technology Landscape – Stable? Volatile?
    - What capabilities exist now? What is emerging?
  - Regulatory Landscape – Stable? Evolving? Uncertain?

Define Requirements in Category

Determine your sourcing approach, portfolio profile for providers in category and relationship structure.

- **Multi- or Single-Sourcing?**
- **What is the optimal mix of Providers in category to address requirements in alignment with my organization's risk tolerance?**
  - Ratio of large vs. small; entrenched vs. new entrant, etc.
- **What relationship structures align to the sourcing strategy?**
  - Preferred vs. Transactional providers

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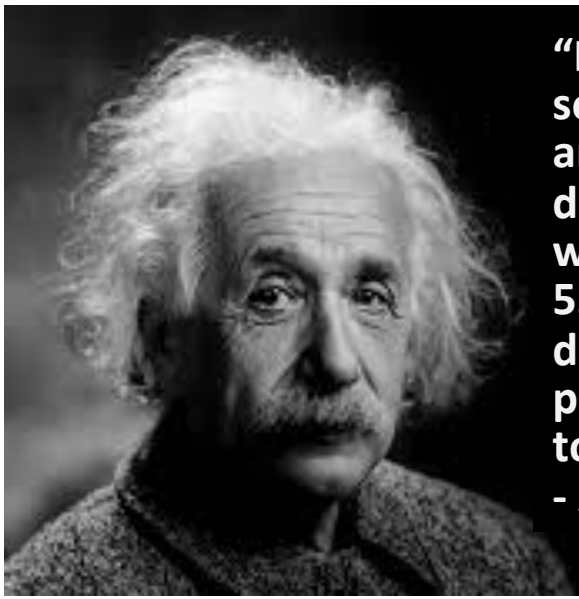
Determining Critical Factors to Consider

Determining the Right Things to Ask

Now that I know what I need and who I should talk to… What are the 'right questions' to ask?

"If you do not know how to ask the right question, you discover nothing."
- W. Edwards Deming



"If I had an hour to solve a problem and my life depended on it, I would use the first 55 minutes determining the proper questions to ask."
- Albert Einstein

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Avoca Quality Consortium™ (AQC)

Bringing together quality, outsourcing, and operational professionals from member pharma, biotech, niche clinical service providers, and CRO organizations to accelerate the development of leading practices and industry standards for proactive quality management and risk mitigation in clinical research.

80+ Member Companies (Sponsors, CROs, Clinical Service Providers)

- **Avoca Research:** Gathering of quantitative and qualitative data from Members; provision of aggregate data and individual benchmarking reports.
- **Leading Practices:** Development of guidelines, tools, approaches, standards, and templates focused on proactive quality management.

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2018 AQC Members

Prequalification Project: Phased Implementation Plan

2014

Phase Zero

Avoca Quality Consortium

Drive Industry Credibility

Define Core Qualification Criteria

Obtain Expert Input

Convene Advisory Board

Develop Core industry Standards and Tools

Target 5 high risk Technical Services

COMPLETE

2014

Phase One

Avoca Quality Consortium

Increase Efficiency

Create Technical Prequalification Standards and Tools

Develop Expert Reviewed Standards and Tools

Develop Prequalification Tools (RFI's, Score Cards, Visit Check Lists) for 4 high risk Technical Services

COMPLETE

2014-2015

Phase Two

Avoca Quality Consortium

Reduce Costs for Prequalification Visits and Mitigate Risk

Share Information

(Standards and Tools)

Develop Portal- for use as a document repository; in 2015 expand to more Technical Services

COMPLETE- STANDARDS AND TOOLS POSTED

2016-Present

Phase Three

Diligent Group Members

Improve Quality through Central Prequalification of Technical Service Providers

Centralize RFIs & Prequalification

Rigorous centralized process to:

- Collect and share completed RFIs
- Prequalify providers against standards

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How the Prequalification Standards are Structured

Taxonomy

Avoca Quality Consortium: Prequalification of Technical Service Providers
Core (Foundational) Industry Standards

#	Brief Standard Identifier	Description of Industry Standard	Regulation/Guidance/ Requirement*	Comments
		COMPUTER SYSTEMS/21CFR PART 11 COMPLIANCE (34)		
CMS 1.0	Electronic Records - Access for Inspections	The business computer systems (including hardware and software), controls, and documentation are readily available for, and subject to, FDA inspection.	21CFR Part 11 Section 11.1 €[xi]	
CMS 2.0	Electronic Records - Closed Systems	Business employs procedures and controls designed to ensure authenticity, integrity, and confidentiality (when appropriate) of electronic records and ensures that signer cannot repudiate signed record.	21CFR Part 11 Section 11.10 (a)-(l)	
CMS 3.0	Electronic Records- Open Systems	The business employs procedures and controls as required for closed systems as shown in previous standard, as well as provides additional measures for document encryption and use of digital signature standards.	21CFR Part 11 Section 11.30 ISO/IEC 27002:2005 10.6.2, Security of Network Services ISO/IEC 27001:2005 12.3.1, Policy on the Use of Cryptographic Controls	This is also applicable to any Cloud[xii] Systems service.
CMS 4.0	Electronic Records – Accuracy	Business maintains "accurate, complete, and current records relating to an investigation". Applies to computerized systems used for records in electronic form that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained, or submitted to health authorities.	21CFR812.140[xiii]	Extrapolated from 21 CFR 812.140(a) for Clinical Investigators; 21 CFR 812.140(b) for Sponsors
CMS 5.0	Electronic Signatures – Signature manifestations	The business ensures that appropriate signature manifestations are implemented. Signed electronic records contain information associated with the signing that clearly indicates the printed name of the signer, the date and time when the signature was executed and the meaning (such as review, approval, responsibility, or authorship) associated with the signature. This information shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	21CFR Part 11 Section 11.50	

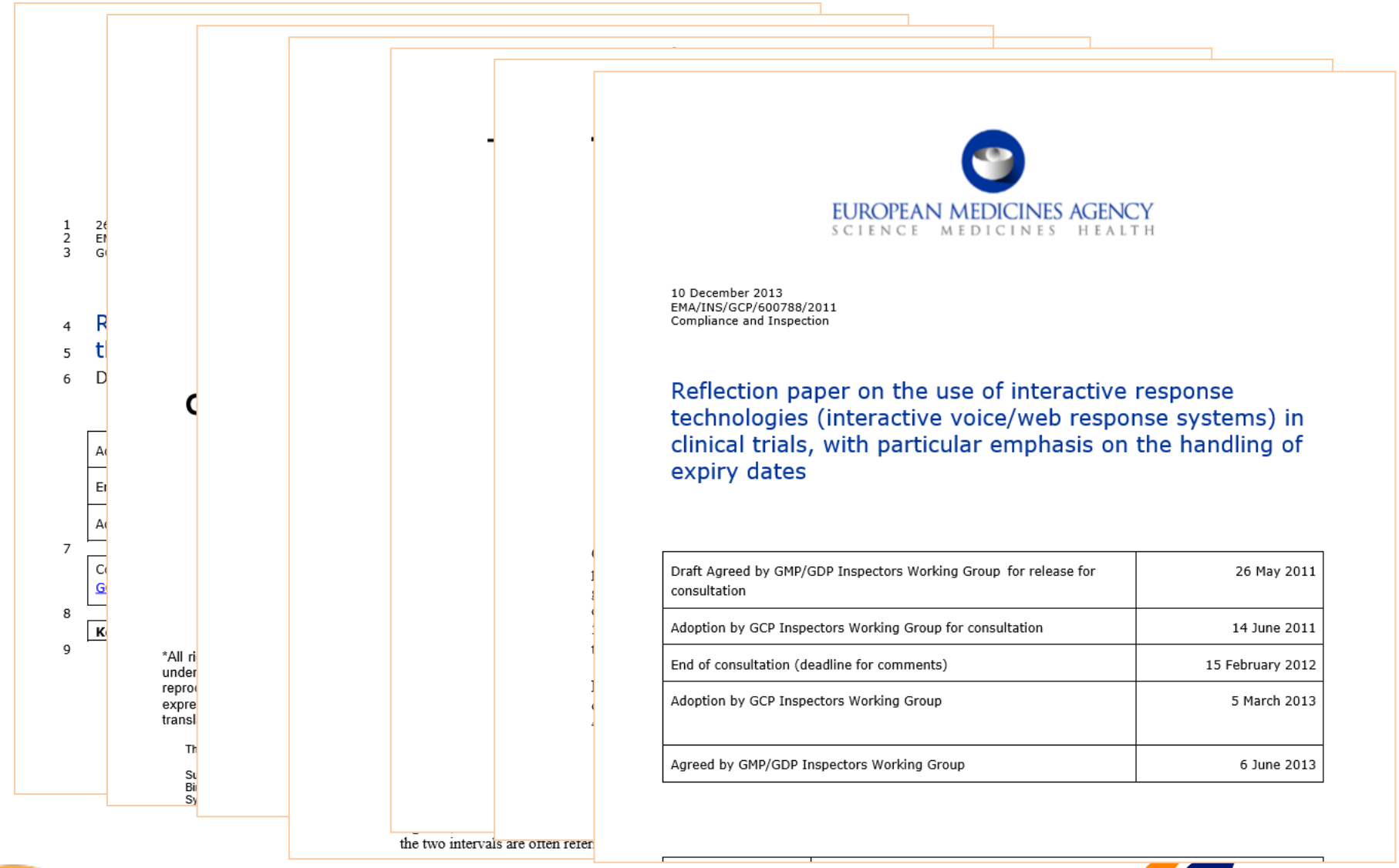
Comments

Label and Description

Mapping

How The Standards Were Mapped

"Technical" Regulations/Guidance Sources



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 December 2013
EMA/INS/GCP/600788/2011
Compliance and Inspection

Reflection paper on the use of interactive response technologies (interactive voice/web response systems) in clinical trials, with particular emphasis on the handling of expiry dates

Draft Agreed by GMP/GDP Inspectors Working Group for release for consultation	26 May 2011
Adoption by GCP Inspectors Working Group for consultation	14 June 2011
End of consultation (deadline for comments)	15 February 2012
Adoption by GCP Inspectors Working Group	5 March 2013
Agreed by GMP/GDP Inspectors Working Group	6 June 2013

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How The Standards Were Reviewed

- Avoca Technical Review - 2 Levels
- Advisory Board Reviews

Core Standards Reviews	Reviewer/s	Status
Amgen	Dylan Bosser	Complete

Central Lab Standards Reviews	Reviewer/s	Status
Amgen	Dylan Bosser	Complete

IxRS Standards Reviews	Reviewers	Status
Amgen	Dylan Bosser	Complete

Medical Imaging Standards Reviews	Reviewers	Status
Amgen	Dylan Bosser	Complete

ECG Standards Reviews	Reviewer/s	Status
Amgen	Dylan Bosser	Complete

Biomarker Lab Standards Reviews	Reviewers	Status
Amgen	Dylan Bosser/Greg Berg/	Complete

Bioanalytical Lab Standards Reviews	Reviewers	Status
Amgen	Anne Merritt	Complete

COA Standards Reviews	Reviewers	Status
Amgen	Anne Merritt, Taras Carpiac, plus 4 other Amgen contributing reviewers	Complete
Merck	Rinol Alaj	Complete
Lilly	Abby Bousum and plus 10 other contributing reviewers	Complete
Takeda	Marilynn Oliphant, plus 3 other Takeda contributing reviewers	Complete
Theorem	Angelika Tillmann	Complete

AQC Member Reviews
(2014 AQC Fall Working Session)

Industry Feedback on AQC Standards

Central Labs (6 of 13)	ECG (4 of 10)	Imaging (7 of 17)	IxRS (8 of 12)	Bio marker (4 of 12)	Bio analytical Labs (2 of 6)	COA (2 of 2)
LabCorp	Bioclinica	Bioclinica	Almac	Apocell	PPD	Corporate Translations
PPD	Bio medical Systems	Bio medical Systems	Bioclinica	Cleveland Heart	PRA	Write Result
Quintiles	CliniLabs	Cascade Medical	Cenduit	PPD		
Synevo	ERT	ICON	Endpoint	Smithers Avanza		
Lab Connect		Image IQ	Medidata			
Covance		PAREXEL	Perceptive			
		World Care Labs/ Proscan	PPD			
			Synteract HCR			

Of 72 companies contacted, 33 (46%) provided feedback.

Determining the Right Things to Ask

- Develop an instrument to collect information with line of sight to its review
- Close the loop with performance monitoring and oversight plans

- **Formulate an assessment that facilitates data collection *and* analysis**

- **Identify parameters that are apt to change due to externalities and/or require more frequent monitoring to align with internal risk appetite and risk controls**
  - Changes to regulations – ICH E6 (R2), GDPR, etc.
  - Financial sustainability

- **Utilize standards for qualification as the basis for oversight and performance management plans**

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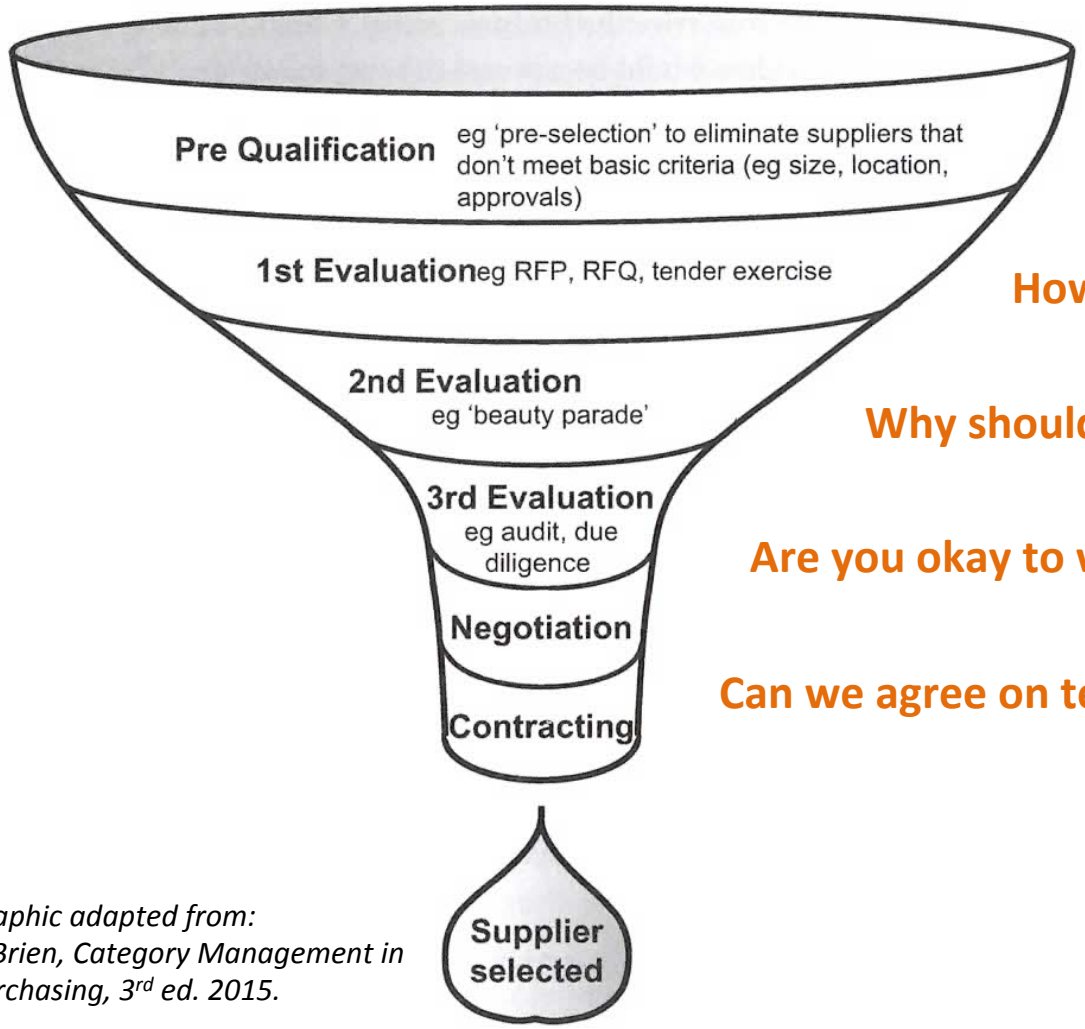
Effective Assessment Tools & Processes

Effective Tools and Processes

Now that I know who and what to ask, how should I do it?



Who's out there?

How much do you cost?

Why should I use you?

Are you okay to work with?

Can we agree on terms?

Graphic adapted from:
O'Brien, Category Management in Purchasing, 3rd ed. 2015.

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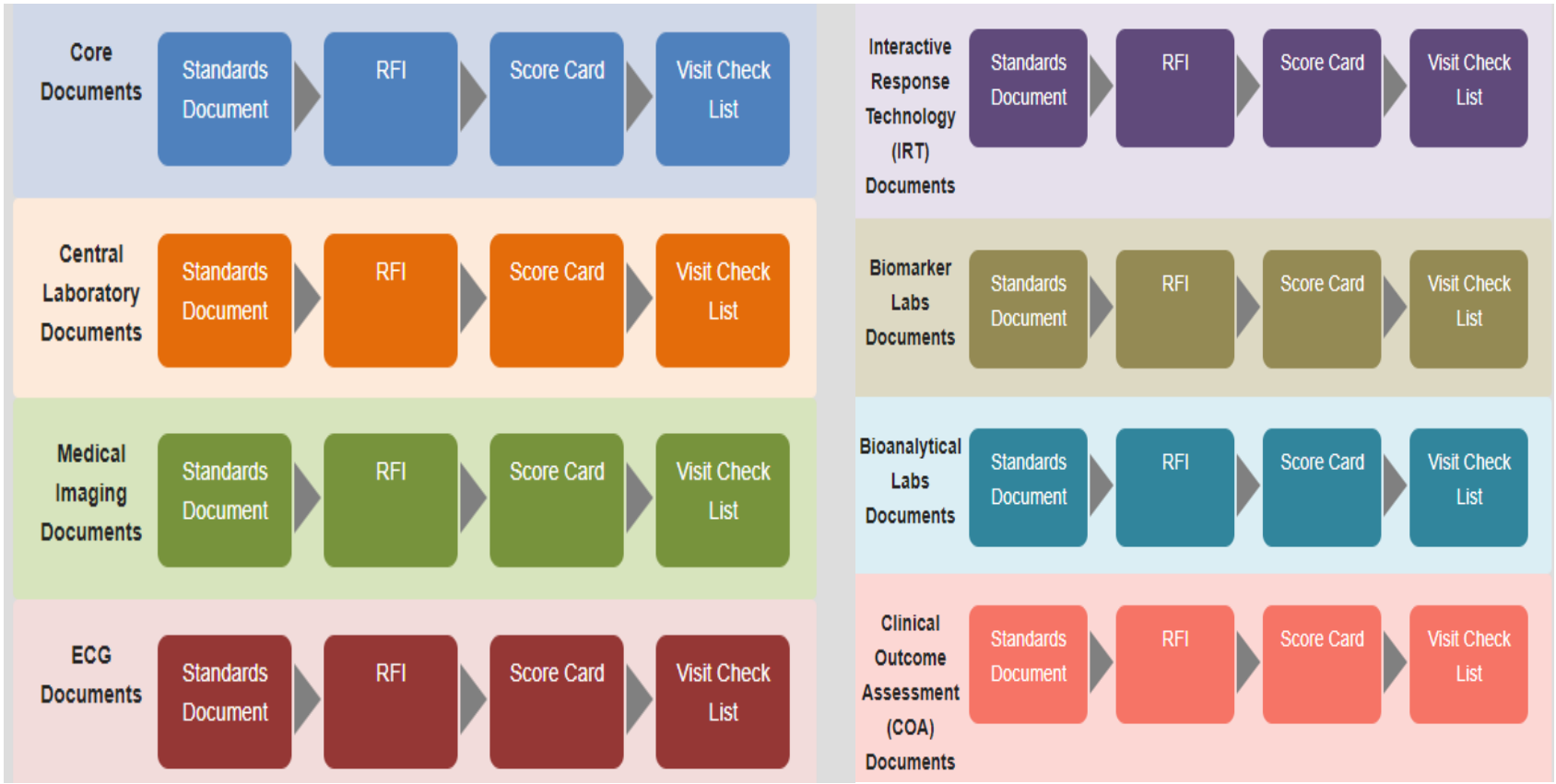
AQC Prequalification Initiative

Current Construct



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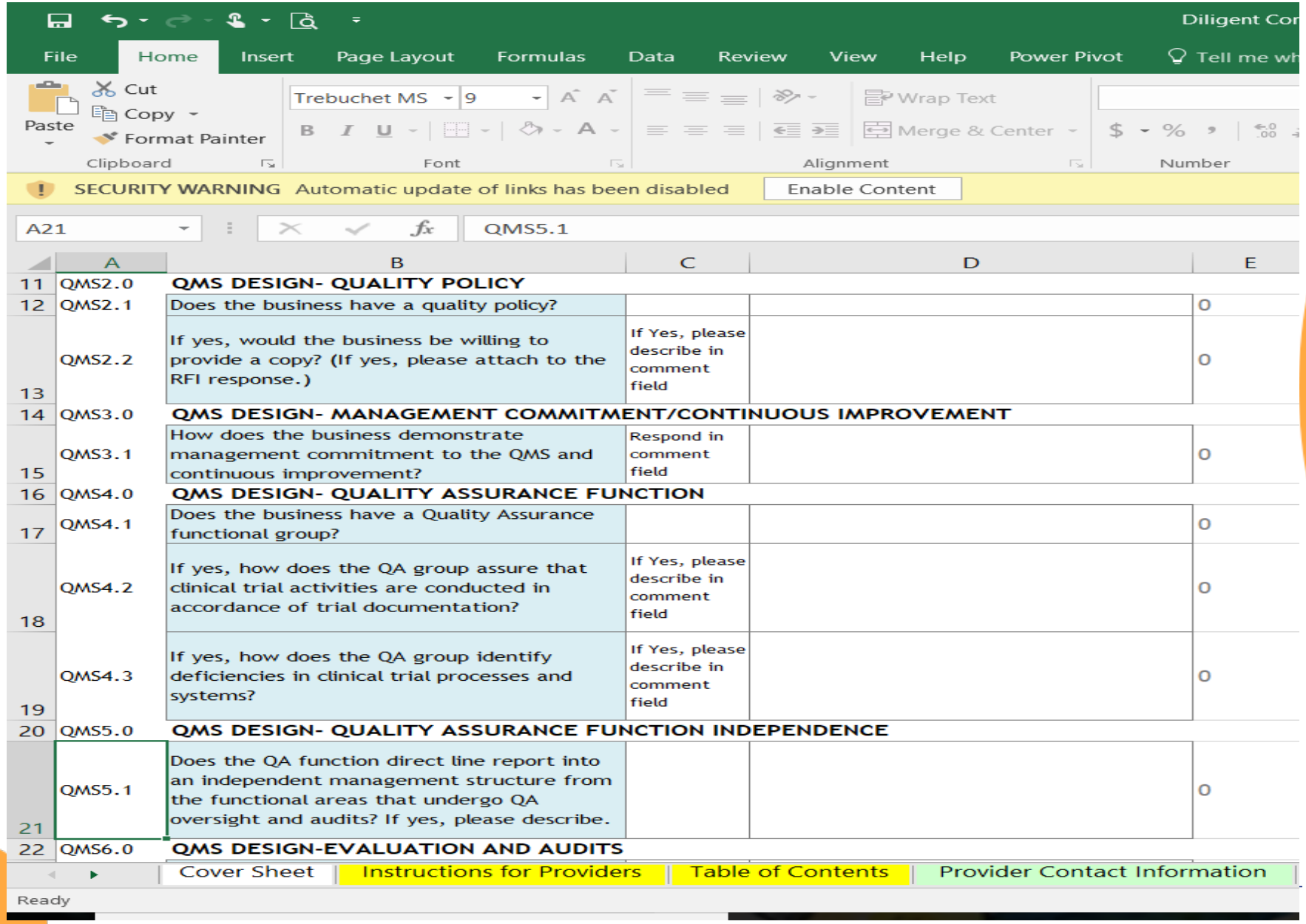
Effective Tools and Processes

RFx: Generic term for the various information gathering activities that shift analysis from the broader marketplace to a short list of defined providers.

- **Request for Information (RFI)**
  - 'Prequalification'
  - Can save time/effort by filtering on basic criteria
  - Focused primarily on the provider

- **Request for Proposal (RFP) / Quote (RFQ)**
  - More specific details regarding a defined opportunity
  - Shorter list of providers having passed prequalification
  - Introduces cost differentiation

Effective Tools and Processes



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A21 | QMS5.1

	A	B	C	D	E
11	QMS2.0	**QMS DESIGN- QUALITY POLICY**			
12	QMS2.1	Does the business have a quality policy?			0
13	QMS2.2	If yes, would the business be willing to provide a copy? (If yes, please attach to the RFI response.)	If Yes, please describe in comment field		0
14	QMS3.0	**QMS DESIGN- MANAGEMENT COMMITMENT/CONTINUOUS IMPROVEMENT**			
15	QMS3.1	How does the business demonstrate management commitment to the QMS and continuous improvement?	Respond in comment field		0
16	QMS4.0	**QMS DESIGN- QUALITY ASSURANCE FUNCTION**			
17	QMS4.1	Does the business have a Quality Assurance functional group?			0
18	QMS4.2	If yes, how does the QA group assure that clinical trial activities are conducted in accordance of trial documentation?	If Yes, please describe in comment field		0
19	QMS4.3	If yes, how does the QA group identify deficiencies in clinical trial processes and systems?	If Yes, please describe in comment field		0
20	QMS5.0	**QMS DESIGN- QUALITY ASSURANCE FUNCTION INDEPENDENCE**			
21	QMS5.1	Does the QA function direct line report into an independent management structure from the functional areas that undergo QA oversight and audits? If yes, please describe.			0
22	QMS6.0	**QMS DESIGN-EVALUATION AND AUDITS**			

Cover Sheet | Instructions for Providers | Table of Contents | Provider Contact Information

Ready

Effective Tools and Processes

Evaluation, Qualification, & Selection: Comparison of different providers' RFx, bid defense presentations, and audits/due diligence findings.

- **Stakeholder Scorecards/Provider Selection Matrix**
  - Weighted scoring of business requirements
  - Qualitative discussion among stakeholders

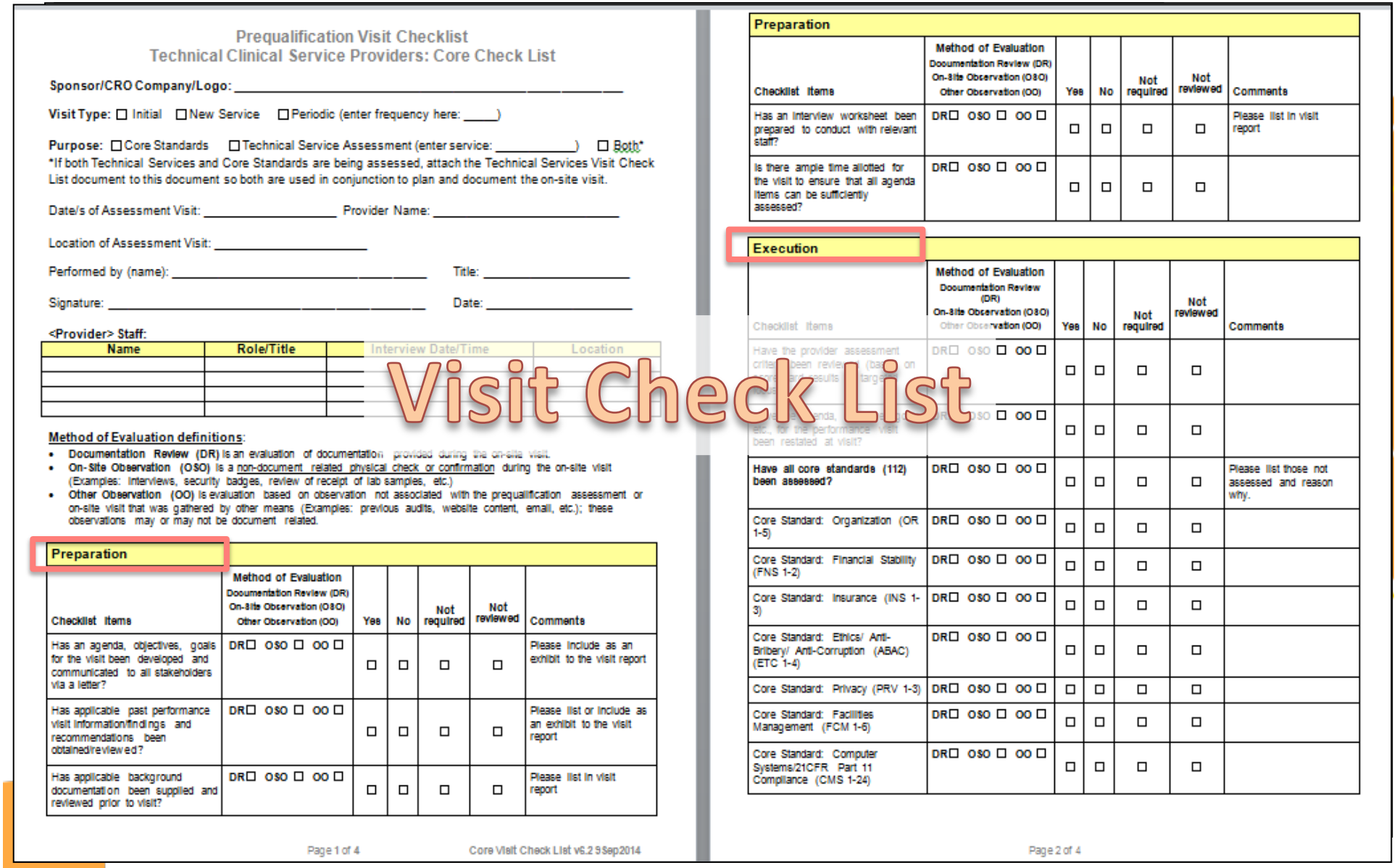
- **Qualification Audits/Site Visits**
  - Evaluation for compliance with regulations and standards
  - Due diligence assessment
  - Audit now, or audit later?

Effective Tools and Processes

Sample RFI Scorecard:

			Stakeholder 1	Stakeholder 2	Stakeholder 3
			No	No	No
Scorecard Dimension	**Description**	**Weight**	**Enter Provider Score**	**Enter Provider Score**	**Enter Provider Score**
Ethics/ Anti-Bribery/Anti-Corruption (ABAC)		5%	0.0%	0.0%	0.0%
Ethical Conduct	Business confidence, integrity, impartiality exist and are free from multiple influences. Confidentiality is maintained and HCC is transparent, reported and compliant.	2%			
Anti-Bribery/Anti- Corruption	Has policy and training.	3%			
Privacy		5%	0.0%	0.0%	0.0%
Privacy Policy/Training	Has a policy, documented practices and trains all individuals to secure personal data.	5%			
Facilities Management		5%	0.0%	0.0%	0.0%
Security-Physical-Logical	Access is controlled to facility and electronic system in place.	2%			

Effective Tools and Processes



Prequalification Visit Checklist
Technical Clinical Service Providers: Core Check List

Sponsor/CRO Company/Logo: _____

Visit Type: ☐ Initial ☐ New Service ☐ Periodic (enter frequency here: ____)

Purpose: ☐ Core Standards ☐ Technical Service Assessment (enter service: _____) ☐ Both*
*If both Technical Services and Core Standards are being assessed, attach the Technical Services Visit Check List document to this document so both are used in conjunction to plan and document the on-site visit.

Date/s of Assessment Visit: _____ Provider Name: _____

Location of Assessment Visit: _____

Performed by (name): _____ Title: _____

Signature: _____ Date: _____

<Provider> Staff:

Name	Role/Title		Interview Date/Time	Location

Visit Check List

Method of Evaluation definitions:

- **Documentation Review (DR)** is an evaluation of documentation provided during the on-site visit.
- **On-Site Observation (OSO)** is a non-document related physical check or confirmation during the on-site visit (Examples: interviews, security badges, review of receipt of lab samples, etc.)
- **Other Observation (OO)** is evaluation based on observation not associated with the prequalification assessment or on-site visit that was gathered by other means (Examples: previous audits, website content, email, etc.); these observations may or may not be document related.

Preparation

Checklist Items	Method of Evaluation (Documentation Review (DR) On-Site Observation (OSO) Other Observation (OO))	Yes	No	Not required	Not reviewed	Comments
Has an agenda, objectives, goals for the visit been developed and communicated to all stakeholders via a letter?	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	Please include as an exhibit to the visit report
Has applicable past performance visit information/findings and recommendations been obtained/reviewed?	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	Please list or include as an exhibit to the visit report
Has applicable background documentation been supplied and reviewed prior to visit?	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	Please list in visit report

Preparation

Checklist Items	Method of Evaluation (Documentation Review (DR) On-Site Observation (OSO) Other Observation (OO))	Yes	No	Not required	Not reviewed	Comments
Has an interview worksheet been prepared to conduct with relevant staff?	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	Please list in visit report
Is there ample time allotted for the visit to ensure that all agenda items can be sufficiently assessed?	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	

Execution

Checklist Items	Method of Evaluation (Documentation Review (DR) On-Site Observation (OSO) Other Observation (OO))	Yes	No	Not required	Not reviewed	Comments
Have the provider assessment criteria been reviewed (based on [illegible] results targeted	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	
[illegible] agenda, [illegible] etc., for the performance visit been restated at visit?	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	
Have all core standards (112) been assessed?	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	Please list those not assessed and reason why.
Core Standard: Organization (OR 1-5)	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	
Core Standard: Financial Stability (FNS 1-2)	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	
Core Standard: Insurance (INS 1-3)	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	
Core Standard: Ethics/ Anti-Bribery/ Anti-Corruption (ABAC) (ETC 1-4)	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	
Core Standard: Privacy (PRV 1-3)	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	
Core Standard: Facilities Management (FCM 1-6)	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	
Core Standard: Computer Systems/21CFR Part 11 Compliance (CMS 1-24)	DR☐ OSO ☐ OO ☐	☐	☐	☐	☐	

Effective Tools and Processes

That is a lot of work – how do I pull that off?

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A Case Study in Centralized Approaches to Qualification

Centralized Approaches

Where have we seen solutions to standardize, centralize, and optimize complex processes before…?

CDISC

Study Data Tabulation Model (SDTM)

match.com
love is complicated. match is simple.℠

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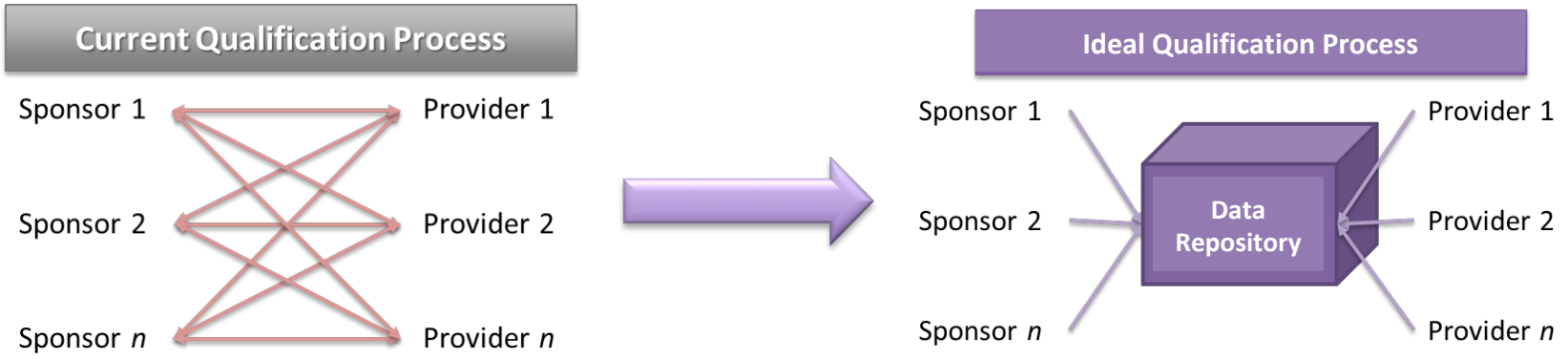
Centralized Approaches

A single, central source of provider information that streamlines the prevalent redundant and dysfunctional model.



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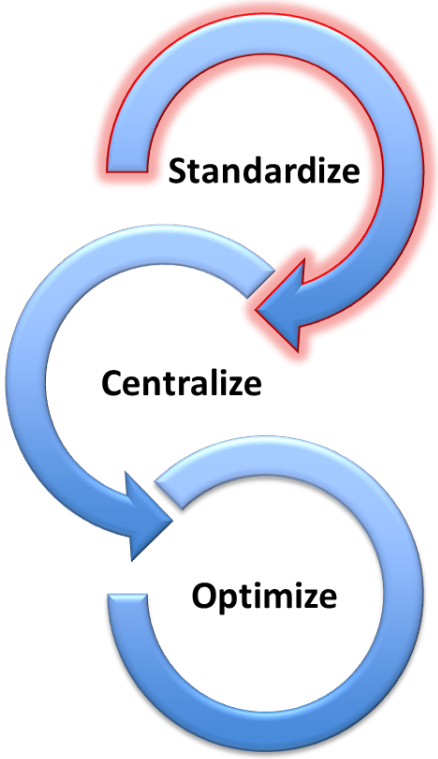
AQC Prequalification Initiative

Standardization **- Eight standardized Prequalification Packages* were created as part of the AQC Prequalification Initiative; the Diligent™ Platform has focused on these high risk, high data generating technical areas:**



- Core Requirements
- Central Laboratories
- IxRS Services
- Central ECG Services
- Medical Imaging Services
- Biomarker Laboratories
- Bioanalytical Laboratories
- Clinical Outcome Assessment Providers

***Each includes a set of Industry Standards, RFI template, Score Card, and Visit Check List which were created as part of the AQC Prequalification Initiative**

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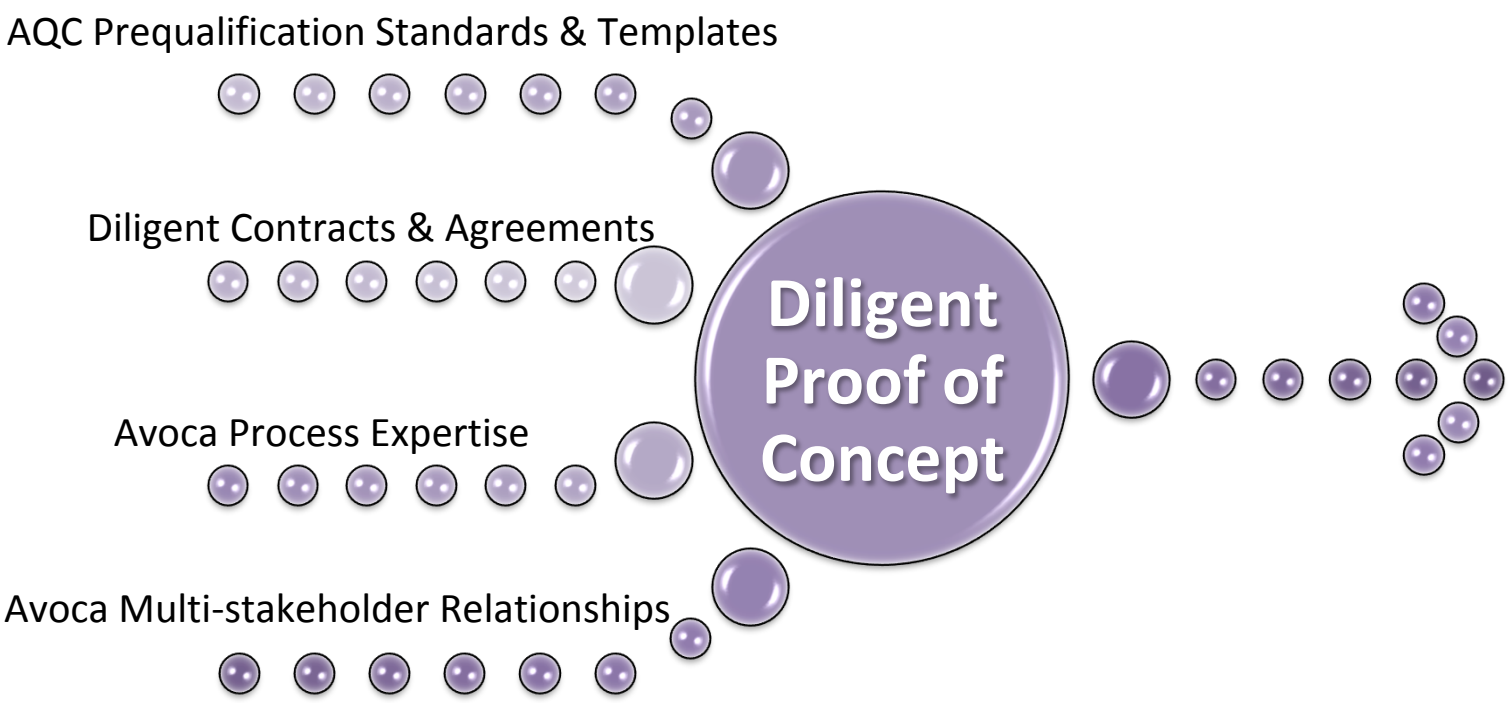
Proof of Concept: Avoca's Diligent™ Centralized RFI Model

Pilot project with the goal to secure 100 completed RFIs in the Diligent central repository



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Centralized Approaches

The pilot was a success.

There are >100 RFIs available across nearly 50 participating Providers.

- Accelovance
- Almac
- Banook- Cardiabase
- BARC
- Biocare Medical
- Biomedical Systems
- BioTelemetry (Cardiocore, VirtualScopics)
- Bracket
- Canfield Scientific
- Cancer Genetics
- Clinical Ink
- Clinical Reference Lab (CRL)
- Cmed
- Covance
- CPC Clinical Research
- eClinical Health
- Eurofins
- Exco Intouch
- Frontage Labs
- Icahn School of Medicine at Mt. Siniai
- iCardiac
- ICON
- Intrinsic Imaging
- IXICO
- Kayentis
- Median Technologies
- MIAC-AG
- NeuroRx
- New York Genome Center
- Perspectum Diagnostics
- PPD
- PRA Health Sciences
- Premier Research
- Q2 Solutions
- QPS Holdings
- Quantificare
- Quintiles
- Sarah Cannon Development Innovations
- Spaulding Clinical
- Syneos Health
- Targos Molecular Pathology
- Translational Drug Development (TD2)
- WorldCare Clinical
- Worldwide Clinical Trials
- WriteResult
- YPrime

Centralized Approaches

The pilot was a success.

Over 150 RFIs have been delivered to participating Sponsors.

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Diligent™ In The News

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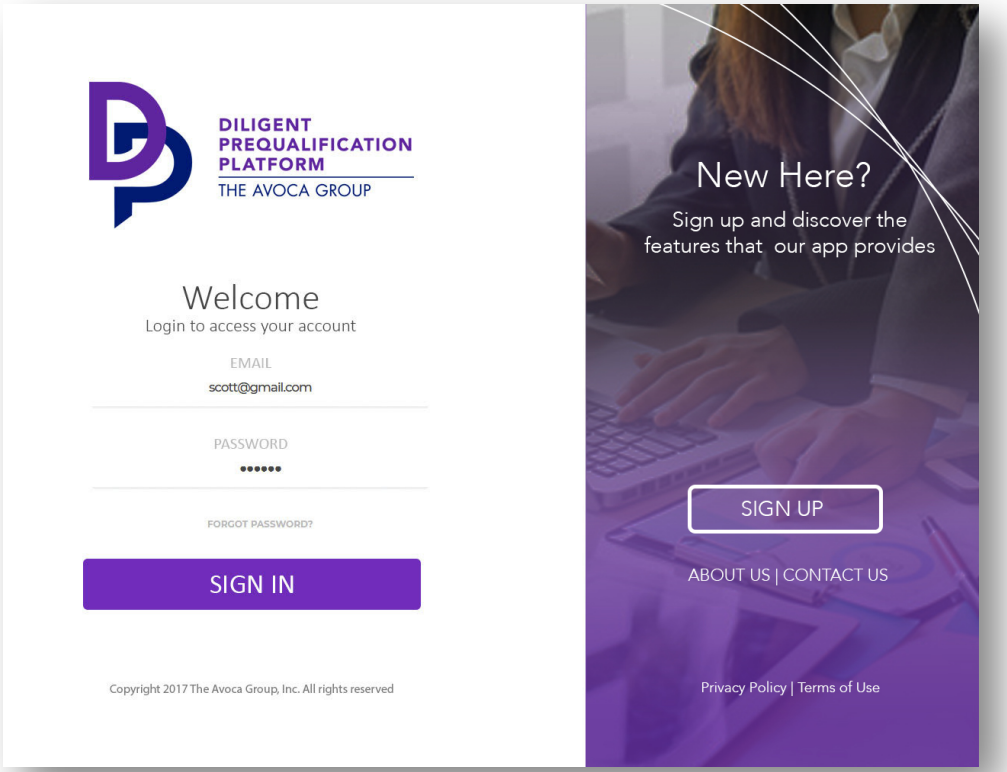
Phase II: Centralized Qualification as a Service and Development of Technology Platform

Expansion to Clinical Service Functions

- Clinical Monitoring
- Data Management
- Medical Writing
- Biostatistics
- Phase I Units

Fit-for-Purpose Technology to Support Clinical Development



DILIGENT PREQUALIFICATION PLATFORM
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Recap

- ✓ Commit to a rigorous introspective evaluation of requirements from all stakeholders to the outsourced services
- ✓ Apprise yourself of external conditions through the lens of risk: threats and opportunities
- ✓ Seek out and leverage industry-accepted standards for evaluating provider qualification
- ✓ Evaluate centralized approaches as a resource to mitigate timeline risk, reduce resource burden, and assure high quality in qualification activities

Questions?

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Thank you!

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