TriTiCon

Selected Experiences

DELIVERY	eClinical Processes & Systems	Strategy & Business Plans	Trial set-up & Execution
eClinical Program Management and eClinical Solution Design DANISH BIOTEC Leading multi-stream eClinical Program, from business requirements analysis, scoping, planning, budgeting to implementation. Program including definition of sourcing model, systems architecture, vendor and systems selection, process design and SOPs, from strategy to implementation and training. Systems and tools including standards MDR/management tool, CDISC checker tool, EDC system, data repository, analysis platform and data browsers.	X	X	
Service Development for ePRO provider US TECHNOLOGY PROVIDER Analysis, design and implementation of enhanced/new data management services. Interviews with clients and internal stakeholders, facilitation of workshops, service definitions and development plan.	X	X	
Development Plan for Clinical Data Management DANISH SMALL-SIZE PHARMA Authoring of long term development plan for Clinical Data Management Unit. Analysis of current and required future state and role. Strategy and development plan to fulfill future role.		X	
EDC System & Vendor Evaluation DANISH SMALL-SIZE PHARMA Defining service and system requirements across all aspects (Functional match, user experience, regulatory requirements, costs, timelines, collaboration) and stakeholders (Sites, Clinical CROs, Data Management, Clinical Operations, Safety, Medical). Evaluation of how different vendor and system combinations meet the requirements, and performs compared to existing system and provider.	X	X	X
Remote Qualification Process for Biometrics CROs DANISH SMALL-SIZE PHARMA Process and templates for remote qualification of CROs. Allowing sponsor to evaluate CROs through review of key documents and SOPs and key questions on central processes and QMS.	X		X
Outsourcing Strategy for Global Data Management DANISH SMALL-SIZE PHARMA Definition, evaluation and recommendation of sourcing models for global data management in Danish pharma.	X	X	
Management of ePRO implementation (trial level) DANISH BIOTECH Management of ePRO vendor selection, set-up, validation and ongoing management, change and issue handling..	X		X

DELIVERY	eClinical Processes & Systems	Strategy & Business Plans	Trial set-up & Execution
Proposal evaluations and sourcing model comparisons for EDC, Data Management and Statistical services. DANISH SMALL-SIZE PHARMA Comparison of sourcing models and proposals for EDC, Data Management, Programming and Statistics services.		X	X
Clinical Systems Architecture Design DANISH SMALL-SIZE PHARMA Definition of architecture and data flow for EDC, ePRO, IVRS/IRT, CTMs and data repository. Systems, data, activity and interchange design.	X	X	
Central Monitoring System Implementation DANISH SMALL-SIZE PHARMA Project management and Consultancy for implementing Central Monitoring Solutions Suite for Trial Management, RBM & Oversight and Medical & Safety Monitoring.	X		
ePRO Solutions and Vendor Evaluation, ePRO Project Management DANISH BIOTECH Evaluation and advice on different ePRO solutions and vendor alternatives. Vendor selection and project management of ePRO implementation.	X		X
Biometrics CRO vendor evaluation and action plan SWEDISH PHARMA START-UP Review and evaluation of data management, programming and statistical services on ongoing trial. Identification of issues and action plan/recommendations.		X	X
Clinical Systems Validation DANISH SMALL-SIZE PHARMA Planning, leading and executing numerous validations of Clinical Data Systems, such as EDC-system, ePRO Solutions, System Interfaces, Visualization Tools. Both on enterprise and trial level.	X		X
Process definitions (and SOPS) for set-up and support of central monitoring tool DANISH SMALL-SIZE PHARMA Design and implementation (SOPs, WI's, Templates) of processes for set-up (Requirements, development, test and UAT) and support (including change management) of central monitoring Apps for Trial Management and Medical monitoring.	X		
eTMF Implementation Consultancy DANISH SMALL-SIZE PHARMA Advise and implementation support for eTMF system implementation.	X		
IRT Implementation Consultancy DANISH SMALL-SIZE PHARMA Advise and implementation support for IRT system implementation.	X		
ePRO Study Reports Development (with partner) US TECHNOLOGY PROVIDER Development and test of trial specific ePRO reports (QlikSense environment).			X
Implementation of Central Monitoring Apps DANISH BIOTECH Project management of implementation apps for trial management, oversight and medical monitoring. Facilitate design of app templates, definition of process for trial specific set-up, oversight, facilitate platform validation.	X		X

	eClinical Processes & Systems	Strategy & Business Plans	Trial set-up & Execution
Support of IRT implementation (trial level) DANISH BIOTECH Advice on IRT set-up and implementation, management of IRT-EDC interface set-up.	X		X
Validation Consultancy for EDC and ePRO systems SWEDISH TECHNOLOGY PROVIDER Identification of applicable guidelines, consolidation of key requirements from guidelines and creation of operational checklists/tools. Definition of validation framework for development of GxP systems.	X	X	
Document handling platform provisioning and document handling SOPs. SWEDISH BIOTECH START-UP Provision of qualified platform (Security, documentation, back-up etc.) for handing of company documents and files. Document handling processes (SOPs) for trial GxP documents.	X	X	
SAE and AE component to EudraCT and CT.gov DANISH MID-SIZE PHARMA Project management and delivery of SAE and AE component to EudraCT and CT.gov. Production of SAS (including XML code) programs for outputs. Production and validation of AE/SAE outputs, and uploading to EudraCT and CT.gov.			X
Deliverables to EudraCT/CT.gov DANISH MID-SIZE PHARMA Implementation of standard software (PharmaCM) for production of deliverables to EudraCT/clinicaltrials.gov. Writing user guidance and training of users. Hand-over to end-users/sponsor.	X		X
Health Economic Market Access Desk Research INTERNATIONAL PHARMA Resource use, costs and effects input data for Nordic region market reimbursement project.			X

Combined skills and experience to meet your challenge

TriTiCon ApS
Sandvejen 30, DK 2665 Vallensbæk Strand, Denmark
The 3 Tiers Consulting Company | www.triticon.com | info@triticon.com

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