The 7 Types of Digital Data Flow (DDF) Personas

- DDF Personas are key roles that can support DDF adoption in your organization.
- Which roles in your organization align to the DDF personas?

Sponsor Company Edition*

Document Purpose

- To assist Sponsor Companies who wish to explore or intend to implement TransCelerate's Digital Data Flow (DDF) solutions
- To identify personnel who are most likely to participate in the implementation and to begin the Change Readiness process

How to Use DDF Personas

- Review generic Personas and the tasks and responsibilities for those roles
- Review example role names and align the Persona roles to roles in your organizations
- Start to identify personnel within your organization who should be involved with Change Readiness for DDF adoption

What This is Not

- A recommendation to change or redefine roles / responsibilities of personnel at Sponsor Companies or other stakeholders
- A complete cross mapping of generic Personas to Company internal roles and titles

Potential Change Impact from DDF

Guide organization & oversee DDF adoption

Task / Responsibility	Brief Description	Example Role Names
Global Regulatory Strategy	• Facilitating alignment on global regulatory strategy for an asset within a Therapeutic/Disease Area and accountable for development and submission of clinical, regulatory, medical and safety documents at the company	• Global Regulatory Affairs Head
Global Data Standards, Collection, Management Strategy	• Accountable for development and adoption of industry & company specific data Standards and implementation of standards for data collection, data management, reporting and analysis	• Global Data Management Head, Standards Head, Global Clinical & Statistical Programming Head
Clinical Drug Development Strategy	• Accountable for framing global clinical strategy for programs within a Therapeutic/Disease Area and approval for study designs, oversight/review of clinical studies for the pharmaceutical products	• Therapeutic Area Head
Clinical Operations Strategy	• Responsible for setting strategy and oversight of company sponsored and supported clinical trials. include study planning, budget management, contracting, and study execution	• Global Clinical Operations Head
Information Technology Strategy	• Responsible for technology solutions and platforms, and provides technical leadership for new and innovative technologies	• Chief Technology Officer
Finance Lead	• Responsible for financial performance, follow-up & expenditures	• Chief Financial Officer

*Exploring developing persona tool for other stakeholder groups

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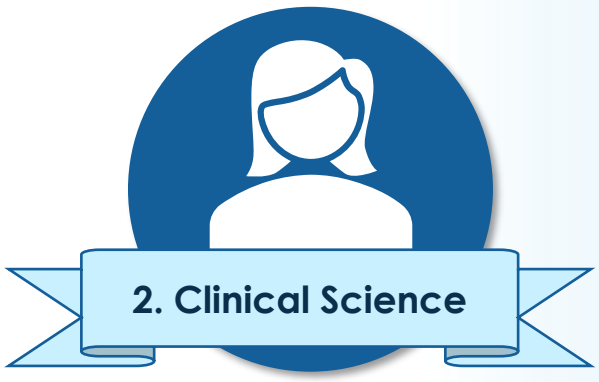

Potential Change Impact from DDF

Provide clinical science expertise & drive DDF adoption

Task/Responsibility	Brief Description	Example Role Names
Responsible for study designs, oversight, review, analysis and approval of clinical studies for the pharmaceutical drug	• Author the clinical development plan and/or protocol synopsis • Authoring the protocol document which serves as the basis for implementing the clinical trial study and provides the groundwork for training materials, budget planning, and other related resources.	• Clinical strategic lead
Provide input into clinical trial design within Therapeutic/ Disease Area	• Responsible for proposing new clinical trials based on area of scientific expertise	• Clinical strategic lead
Responsible for defining details that will be used in authoring the protocol elements and sections	• Investigate scientific data and perform literature reviews, engage with clinical leadership to inform potential clinical trial proposals. • Plan study designs based on clinical leadership's input, which are utilized in the subsequent protocol authoring.	• Clinical Scientist • Medical Scientist • Medical Monitor
Design/Develop study parameters	• Design scientific frameworks that align with goals of the study and the overall development plan for the drug. • Lead a cross-functional team to review and incorporate practical aspects of the study	• Clinical Scientist • Medical Scientist • Medical Monitor
Review historical study designs, objectives, etc..	• Leverage existing study design templates from studies and gather insights for future protocol developments	• Clinical Scientist • Medical Scientist • Medical Monitor
Draft/implement protocol amendments as required	• Will include making the study design adjustments as required as well as editing of the supporting documentation.	• Clinical Scientist • Medical Scientist • Medical Monitor

Task / Responsibility	Brief Description of Task	Example Role Names
Oversee planning, development, implementation, and security of company's information systems	• Technology leadership-approve technology solutions	• R&D IT Lead
Preparing technology roadmap for the organization	• Clarify and/or influence the evolution of technology or roadmap and its applicability to the organization	• R&D IT Lead
Ensuring IT organization capabilities (people) are ready for future state	• Build plan to develop technical skills of IT staff • Encourages and influences IT and wider organization to adopt new tools, applications, and industry technology trends, including GenAI	• R&D IT Lead

Potential Change Impact from DDF

Provide technical strategic leadership & drive DDF adoption

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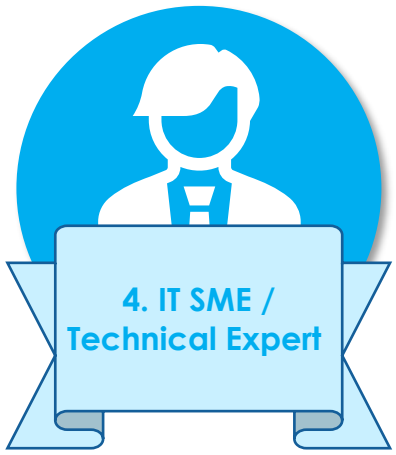
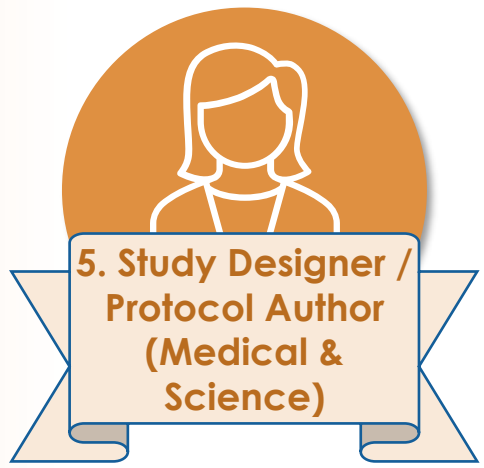


Potential Change Impact from DDF

Provide technical expertise & execute on solution updates for DDF adoption

Task / Responsibility	Brief Description	Example Role Names
IT Infrastructure build and development	• Continually assess and advise IT leadership on current state of IT infrastructure and in context of future state	• IT Software Architect • IT Infrastructure Architect • IT Data Management • IT Business Analyst
IT capabilities	• Continually develop / train themselves and their teams on technology stack in their organization	• IT Software Architect • IT Infrastructure Architect • IT Data Management • IT Business Analyst
Implement new tools and applications	• Install, operationalize and support new IT tools and applications e.g. DDF MVP for the organization to be ready to use • Integrations with external systems. • Influence Roadmap of vendor supplier. • Managing vendor supplier validation, upgrades & access management	• IT Software Architect • IT Infrastructure Architect • IT Data Management • IT Business Analyst
IT Infrastructure build and development	• Continually assess and advise IT leadership on current state of IT infrastructure and in context of future state	• IT Software Architect • IT Infrastructure Architect • IT Data Management • IT Business Analyst

Task / Responsibility	Brief Description	Example Role Names	
Review historical study designs, objectives, etc.	Leverage existing design templates from studies, gather patient & investigator insights, and leverage internal & external data/insights for future protocol developments	• Study Designer/ Builder • Clinical Data Manager • Clinical Design Analytics	• Medical Writer • Medical Science Expert • Patient Engagement Lead
Design/develop study parameters	Create scientific design in line with study objectives & molecule development, and lead cross functional collaboration and review & input operational components	• Clinical Scientist/ Medical Scientist • Medical Monitor • Biostatistician	• Bio sample/ PK scientist • Program lead/Molecule lead
Create/draft the protocol document & operationalize the study	Create/author the protocol document that will facilitate execution of the clinical trial, and serve as the foundation for training and support materials, budgeting, materials, etc.	• Medical Writer • Clinical Scientist/ Medical Scientist • Study Medical Expert	• Biostatistician • Bio sample / PK scientist
Draft/ implement protocol amendments as required	Includes making study design adjustments as required as well as editing of the supporting documentation.	• Medical Writer • Clinical Scientist/ Medical Scientist • Study Medical Expert • Biostatistician	• Bio sample/ PK scientist • Study Designer/ Builder • Clinical Data Manager



Potential Change Impact from DDF

Work in a new way using a Digital Protocol and/or adhere to protocol standards

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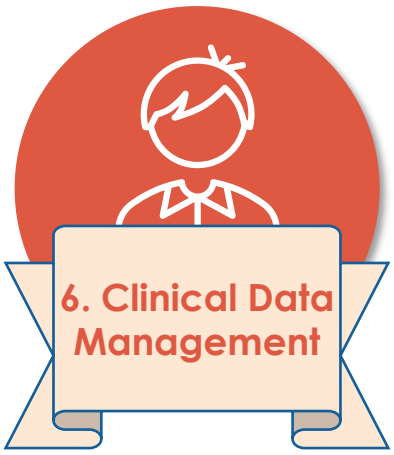


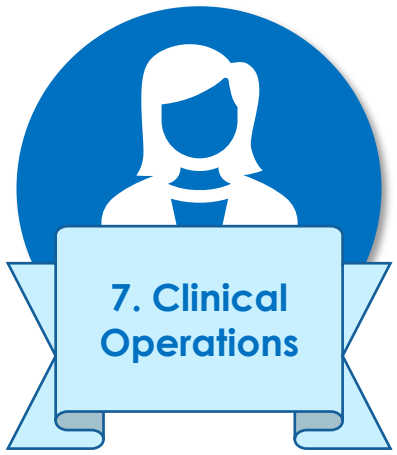
Potential Change Impact from DDF

Leverage some auto-configuration as a result of a Digital Protocol and/or adherence to standards

Task / Responsibility	Brief Description of Task	Example Role Names
Pre-study activities	Contribute to Study Design	• Biostatistician • Clinical Data Manager
Study start up programming	SoA set-up by standards selected, programming of EDC, Statistical Analysis Plan	• Clinical Data Manager • Clinical Data Programmer • Standards Programmer • Biostatistician
Study Conduct Management	TLF programming, Amendment Management, Data entry review, query management, data review (e.g. futility analysis, data monitoring committee), narratives generation, STDM	• Clinical Data Manager • Biostatistician
Study Close-out	Clean data base, finalize TLF	• Clinical Data Manager • Statistical Programmer • Biostatistician
Creating and maintaining standards	Creation of templates for users, and therapeutically aligned standards	• Clinical Data Manager

Task / Responsibility	Brief Description	Example Role Names	
Pre-study activities	Contribute to Study Design, Identify countries and sites in scope, EC (& HA) submission, contracting	• Feasibility specialists • Contract Specialists	• CTA • Clinical Project Manager
Study start up trial related	Site selection, prepare sites for ready to enroll, coordination of countries involved, training of site personnel & study team, budgeting	• Start-up specialists • Clinical Research Associate • Clinical Project Manager • Country Lead Monitor	• Study Lead Monitor • Study Manager • Study Audit Lead • Finance • Global Trial Manager
Study Conduct Management	Coordination of sites and countries, issue management, study drug management, inspection & audit management	• Study Managers / Trial Manager • Clinical Research Associate • Clinical Project Manager • Country Lead Monitor	• Study Lead Monitor • Study Manager • Study Audit Lead • Global Trial Manager • Clinical Data Manager
Study Drug Safety**	Perform safety review of data, SUSAR distribution, investigator brochure	• Safety Surveillance • Medical & Science Specialist	• Medical Experts • Pharmacovigilance
Study Close-out*	CSR (Provision of appendix 16 documents & participation in CSR review), Dossier creation for submission, close-out of sites, archiving	• Regulatory Affairs/Submission Management • Medical Writer • Study Manager	• Study Lead Monitor • Clinical Trial Associate • (Study Medical Expert) • Country Lead Monitor

**Roles may extend beyond Clin Ops



Potential Change Impact from DDF

Leverage some auto-configuration and data re-use as a result of a Digital Protocol and/or adherence to standards

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