The 6 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
Medical Writing/ Clinical Reporting leader	• Responsible for the development of clinical, regulatory, medical and safety documents at the company	• Regulatory Affairs Lead
Data Management and Analytics Leader	• Responsible for Data Standards, data base set-up, data collection and monitoring data and analysis	• Data Science Lead
Clinical trial operations leader	• Responsible for managing of company sponsored and supported clinical trials. include study planning, budget management, contracting, study execution,	• Clinical Drug Development Lead
Scientist leader	• Responsible for study designs, oversight, review, analysis and approval of clinical studies for the pharmaceutical products	• Clinical Drug Development Lead
Finance Lead	• Responsible for financial performance, follow-up & expenditures	• Finance Lead

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 the evolution of technology 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	• R&D IT Lead

Potential Change Impact from DDF

Provide technical strategic leadership & drive DDF adoption

*Exploring developing persona tool for other stakeholder groups

The 6 Types of Digital Data Flow (DDF) Personas

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Which roles in our organization align to the DDF personas?

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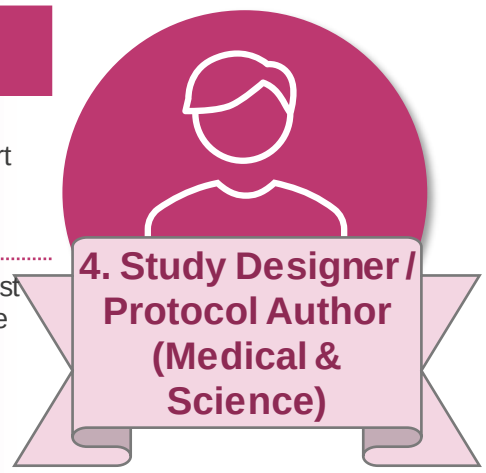
Potential Change Impact from DDF

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	• 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 insights for future protocol developments	• Study Designer/ Builder • Clinical Data Manager	• Medical Writer • Medical Science Expert
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

*Exploring developing persona tool for other stakeholder groups

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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	• 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	• 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 • CLM • 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	• 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

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