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data Blueprint

LSCP+

ENTERPRISE DATA GOVERNANCE (EDG)

"UNLOCKING BUSINESS VALUE THROUGH INFORMATION MANAGEMENT"

– says Peter

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The contents in this document have been mutually developed by

LSCP and **Data Blueprint,** jointly referred to as **LSCP+:**

The document takes into consideration the introduction of the ISO IDMP, ICSR & SPL Standards, hereafter referred to as **IDMP+**, introducing requirements for a much higher information granularity, for both Industry & Regulators alike, in view of bringing safer drugs to patients.

An "Ideal Momentum"

EXECUTIVE SUMMARY

The Pharmaceutical Industry and Health Authorities (HA) have undertaken an effort to harmonize global data by the implementation of the new ISO Identification of Medicinal Products (IDMP) and related Standards. These additional standards include the ISO Individual Case Safety Reports (ICSR) and ISO Structured Product Labeling (SPL) and are herein collectively called **IDMP+.** All three are aimed at improving communication and patient safety on a global scale.
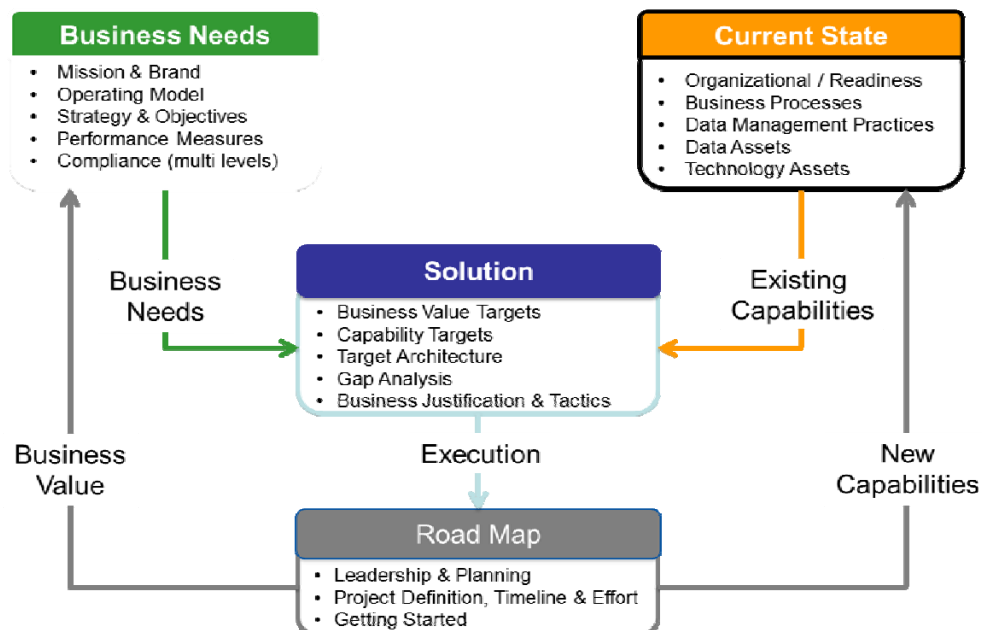
In order to satisfy the governance of data according to **LSCP**'s approach to **IDMP+**, higher content granularity is required, leading to an increased number of information components and associated metadata. The move to manage a large number of smaller documents requires a thorough revision to Enterprise Information Management, which includes Data Governance and Quality considerations across three major dimensions:

1 Recognizing the value of information as an asset;
2 Elevating standards not as a burden, but as a real business opportunity
3 Strategizing the cross-functional application of **IDMP+**

This paper provides an overview of the **IDMP+** approach that will address each of these areas as they should be covered in an Enterprise Information Management Process.

LSCP has teamed up with **Data Blueprint** to create this approach in the context of **IDMP+**. It is critical to get this project organized and executed in a pragmatic way with actionable information and clear, documented decisions!

Data Strategy Framework

Business Needs
- Mission & Brand
- Operating Model
- Strategy & Objectives
- Performance Measures
- Compliance (multi levels)

Current State
- Organizational / Readiness
- Business Processes
- Data Management Practices
- Data Assets
- Technology Assets

Solution
- Business Value Targets
- Capability Targets
- Target Architecture
- Gap Analysis
- Business Justification & Tactics

Business Needs

Existing Capabilities

Business Value

Execution

New Capabilities

Road Map
- Leadership & Planning
- Project Definition, Timeline & Effort
- Getting Started

Our mutual Mission

It is our belief that data in any format, media, structure, depth, etc. is the most powerful yet underutilized asset in business today. Poor practices in managing data are widespread and many organizations are unaware of the true state of their data capabilities. We assist Life Sciences clients to succeed by strengthening their capabilities for managing their data, providing tailored solutions that meet business requirements for the future and building lasting partnerships.

In order to succeed in today's information-driven environment, data needs to be at the heart of your organizational business model and strategy. This is where we propose to join: We put organizations on the mutually agreed, right path to leverage their data for competitive advantage and unlock business value in the innovation process (an example). We help you to recognize and then comply with legal and regulatory requirements. We help you to manage business risks through a better use of the company's data. Our approach leverages core competencies, including foundational data management practices such as Enterprise Data Strategy, Data Governance, Data Architecture and data education. When technical data is integrated with good records management practices, including the improvement of Data Quality, Data Integration, incl. Mobile Devices and Social Media, Data Platforms and Business Intelligence, the business value will increase.

All these activities can be developed and executed in a _pragmatic way_, alongside your **IDMP+** step-wise implementation program/project while identifying the data interdependencies. We would start with an awareness verification step, part of the **LSCP+** Option 1 implementation process.

1   Data Strategy –
Stay ahead of the competition. Align your data with your business / regulatory strategy

- Does your organization have a data strategy for winning in the evolving information-driven market place?
- Does your organization struggle to deliver on data-centric initiatives?
- Does your organization truly think of and manage data as a strategic asset?
- Does your organization think data is owned and managed by IT or by the business?

Companies that fail to implement information-based business strategies will be left behind. A data strategy outlines your organization's vision for managing data as an asset and its plans for leveraging data to create a competitive advantage. As trends in the market place and regulations such as IDMP become more data-driven, a data-focused business strategy is an imperative. The data **strategy needs to align directly to the organization's business strategy and operating model.**

LSCP+ DATA STRATEGY EXPERTISE

Understanding how data strategy can drive your business' success

We are focused on delivering measurable business value – this can only be done if we understand your business needs and operating environment. Our consultants analyze your

business strategy – where information is created, used, deployed and for what purpose. These are essential elements as we develop the business requirements for your data strategy.

Identifying existing data management capability gaps

With a team of Certified Data Management Professionals (CDMP) will conduct a comprehensive assessment of your existing data management practices, skill sets and data technologies. Combined with **LSCP+** experts in Life Sciences, the strategy will be focused on industry business objectives and issues. Gaps in existing capabilities are based on understanding where your organization is heading in terms of your business strategy.

Building a business-focused data strategy

Our recommended data strategy combines developing foundational data management capabilities with the development of business-integrated technical data solutions. This ensures you are building focused data solutions while evolving and sustaining an organizational data management capability through your data strategy.

WHAT MAKES THE **LSCP+** DATA STRATEGY APPROACH DIFFERENT

Tailored data strategy

Our approach tailors the data strategy to address your most important business needs. We do not have a "one-strategy-fits-all" approach. We understand each organization has a unique position in the market and that your data strategy must fit your specific business needs.

Strengthen your capabilities for managing your data

Our highly collaborative approach is committed to strengthening your organizational data management capabilities. We believe that in order for your organization to effectively leverage data as an asset (and have a competitive advantage in the information-driven market place) you must have a strong data management foundation.

Build lasting partnerships

Our approach is to be there beyond the engagement. We continue to meet and offer valuable resources to our clients because we understand that this change is transformational for most organizations. This can include helping clients find qualified data management resources to hire or providing additional training through webinars and other educational programs.

2 Data Governance Strategy – Protect your mission critical data assets

- Do you manage your data assets with the same discipline and rigor as the CFO manages financial assets or that HR manages human capital?
- Definitions: Is it clear who in the organization is responsible for managing your data assets? Are the responsibilities of related operational units well defined?

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- Have you trained the entire organization in your data governance policies, processes, roles and responsibilities? Are they clearly understood?
- Are your data governance principles "embedded" into your daily operational processes?
- Does the organization understand that these organizations and technology exist to meet the needs of the business?

Data and information technology do not exist for their own sake. Data governance is the exercise of authority and control over the management of your mission critical data assets. It is the data governance function that guides how all other data management functions are performed.

LSCP+ DATA GOVERNANCE EXPERTISE

Defining your data governance requirements

- We evaluate and understand your current state, including current roles and responsibilities, policies and processes
- We define the business needs of a data governance program along with the business problems that need to be solved
- We inventory and define the critical data domain and attributes, including how the data is created and used within your business processes

Developing a data governance framework

- We help to develop/enhance your data governance charter, policies and processes, including guidelines on how to enforce rules, manage conflicts and on how to integrate principles and policies into daily operations
- We help to develop/extend your data governance organizational structures along with their roles and responsibilities, governance council, working groups and data stewards
- We help to develop/implement the meta-organizational structure – e.g. centralized or federated data governance

Implementing data governance alongside your IDMP program

- We help you to develop a roadmap including short-term wins and long-term milestones
- We provide guidance and support for change management, education, communication and training efforts
- We provide guidance and support in the execution of data governance projects

WHAT MAKES THE **LSCP+** DATA GOVERNANCE APPROACH DIFFERENT

Tailor your solution to the most impactful data governance processes

We understand that governance can seem like an added bureaucratic layer with little additional value. That is why we take an *agile* approach to developing governance where it matters the most. We propose a "crawl – walk – run" approach. Start small and build as executive level and

departmental buy-in is gained and the organization matures its governance practices.

Leverage Industry Thought Leaders

Our **LSCP+** industry thought leaders have substantially contributed to the concept on data governance. They address cultural issues and support by leading organizational change. They will develop processes and provide training that supports collaboration across functional areas.

3   Data Architecture - Organize your data to meet the needs of your business

- Can you easily access, integrate and share information across your organization?
- Have you eliminated data redundancy across your enterprise?
- Do you struggle to extract the value from your data because it is too cumbersome to navigate and access?
- Do you struggle accessing your historic data that **may** still have business relevance?
- Do you have a blueprint of all your data assets and how they are related?
- Are you confident your data is organized to meet the needs of your business?

Organizations are facing an ever-growing variety and volume of data. Data Architecture organizes your data assets so they can be leveraged in your business strategy to create real value to your business. Data Architecture is foundational to an information-based operational environment.

LSCP+ DATA ARCHITECTURE EXPERTISE

Defining your data architecture requirements

- We create data-centric models of your business and align the activities that will drive your organization's competitive advantage
- We assess your organization's data architecture skills, organizational roles and responsibilities, practices, technologies and effectiveness
- We identify the gaps between your business needs and our assessment results to define requirements for the most cost-effective data architectural solution

*Creating a data architecture in line with **IDMP+** requirements*

- We create data architecture solutions that organize and manage the complexity and volume of your data assets so they align to your business and regulatory strategy
- We use your business and operational requirements to develop conceptual, logical and physical data architectural models
- We define a common language for the most important data elements that helps foster a collaborative business knowledge base across your organization

Implementing a data architecture best practice

- We help you plan and create the processes, policies, workflows, organizational structures and skill sets needed to sustain your data architecture
- We deliver training and education for data architecture on a variety of levels including mentoring, workshops, certification training and college credits

WHAT MAKES THE **LSCP+** DATA ARCHITECTURE APPROACH DIFFERENT

We view your data assets through a business-focused lens

- We ask questions about your business to understand your data architecture needs
- We tailor our solutions to meet your most impactful business and regulatory needs – we unlock the business value of your data
- We avoid the boil-the-ocean approach – based on our scientific research, we understand that in most cases it's really only 5 to 10% of your data that is critical to driving business value

We assist you in the creation of a foundational data architecture capability

- Your organization must have a data architectural competency to succeed in a data-driven economy. We use our collaborative approach to transfer our knowledge and expertise to your organization and position you for success
- In addition, our industry recognized thought-leaders can provide the training and mentoring to evolve your organization's data architecture skills

4   Data Quality –
We prefer "First Time Correct" over "Find and Fix"

- How is data quality defined in your organization?
- Do you know what your most important data is?
- Do you trust your most important data? Is it accurate and concise?
- Do you have objective criteria to define what is important and what is supportive data?
- Do you get multiple answers to the same question, depending on who you ask or what data you access?
- Does your organization "find-and-fix" data quality issues when they are uncovered or do they go back to the root cause to fix the issues – a "first time correct" approach?
- Have you noticed how often your employees are double-checking the data before they use it or correct a cut-and-paste action? Does this make you more or less confident in the data?

In terms of **IDMP+**, data quality is the basis for relevant regulatory compliance. Our data quality solutions are driven from the simple principle of "first time correct" and the implementation of the Quality by Design (QbD) approach. We start with the definition of what quality means to your organization and your customers / target audiences and focus on your most important data assets. As an example in clinical, ensure our solutions address the root cause of any quality

issues so that your data is correct for your target audience (IDMP and Authority information exchange) when it is first created. Our experience has shown that organizations can never solve their data quality issues if they only use the "find-and-fix" approach.

LSCP+ DATA QUALITY EXPERTISE

*Identifying data quality issues and measuring their impact, including **IDMP+** perspective*

- We help to identify your most important data and develop business requirements for data quality rules, including QbD
- We help by developing a data
- quality rules engine that is integrated with your operational data flows that will define and monitor data quality
- We help you to quantify the business impact of discovered data quality issues

Remediating the root cause for data quality deficiencies

- We analyze your data quality issues from the rules engine to identify and understand the root cause for data quality deficiencies
- We propose and implement data quality solutions to address this root cause and, when needed, we develop a business case for remediating and corrective actions
- We build in-process controls to ensure that data quality issues are addressed going forward
- When needed, and only after remediating the root cause, we correct existing erroneous data

Implementing a data quality framework

- We broadly evaluate the existing data quality issues and organizational challenges creating those issues
- We create an achievable scope for the framework by identifying your organization's most important data assets (usually 5-10% of the data, at most)
- We help developing an operating framework that leverages people, processes and technology to address the gaps in data quality management, including organizational cultural challenges
- We help to craft and support the implementation of a roadmap that delivers short-term wins and sets long-term milestones

WHAT MAKES THE **LSCP+** DATA QUALITY APPROACH DIFFERENT

Solutions tailored to your most important data assets

We understand that only a portion of the data your company captures is truly impactful to your business. Our expert consultants will work closely with you to define objective criteria for identifying the most important data assets to your business by understanding your business model in data terms.

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Leverage Industry Thought Leaders

Our IDMP industry thought leaders, such as Dr. Beat Widler, Dr. Dimitri Stamatiadis and Ruedi F. Blattmann have substantially contributed to the concept on data quality. This is extremely important to *reach **IDMP+** compliance and avoid validation setbacks*! If poor data quality is pervasive and disruptive to your organization, our thought leaders can help re-orient the organizational thinking and culture to manage data as an asset.

Create an organizational capability to maintain high data quality

In order to compete in today's information-based economy, the practice of ensuring high data quality for your most important data assets is a pre-requisite. Our collaborative approach will transfer our knowledge and skills to your organization so that you can create a core competency in data quality. In addition, our industry recognized thought leaders can provide training and mentoring to evolve your organization's data architecture skills.

5 Data Integration – Data-centric organization requires Unified Data

- Can you easily measure key business metrics across your enterprise silos?
- Have you noticed in how many places the same data exists across your organization?
- Do you get different answers to the same questions, depending on whom you ask or where you look for the answers?
- Do you notice it takes an unexpected level of effort to answer some simple business questions?

Data integration across organizational silos creates new insights about your customers, target audiences, products, marketing channels and your financial and operational performance while fostering a culture for greatly improved data availability and accuracy. It is also the biggest challenge. Whether your organization is developing a Big Data solution or creating regulatory financial reports – data integration is at the heart of these solutions.

LSCP+ DATA INTEGRATION EXPERTISE

Data Integration based on your business term

An organization can only be integrated if they use a common language to communicate. With our clients, we create a repository of meaningful business-terms and then use these terms to build integrated data flows for sharing data across the enterprise.

Enabling a more integrated business model

We enable you to view your business from multiple perspectives. We can design and develop integrated data flows, making your data more visible, accessible and understandable to the different business stakeholders.

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Recommending and using technology to build the integrated platform

With the ever-increasing volume and variety of data and the expected benefits of data integration, we can design and implement a technical framework for moving, transforming and sharing data across your organization.

WHAT MAKES THE **LSCP+** DATA INTEGRATION APPROACH DIFFERENT

Focus on your business needs

We take a management consulting approach to delivering value with our data integration solutions. Typically, it's when you are able to look across business silos that value gets created with your data. We focus on where those data integration points are most impactful to the business.

Make data integration an organizational capability

An integrated data environment can only be successfully developed and sustained when you have a strong foundation in managing data including data governance and data architecture. Our team works collaboratively and can provide the skills training needed for your organization to develop data integration as a core capability.

Build data integration for the long-term

Most data integration occurs at the project level. We, however, understand that to sustain an integrated data environment, it has to be driven from the top-down. Our approach starts with an enterprise view of your business needs and mapping your data assets to those needs of today and in the future. We develop our data integration solutions so that the data lineage is captured and documented. This ensures there is transparency and understanding as your data moves across the organization.

6 Data Platform – No one can address all of your problems

- Do you want insights on your customer's behavior?
- Do you need real-time customer transactional information?
- Do you need historical data or just access to the latest transactions?
- Where do you go to find the single version of the truth about your customers?
- Do you want to measure critical operational process performance?
- How do you intend to manage IDMP for substances (GInAS)?

No one data platform can answer all these questions. This is commonly misunderstood and often leads to very expensive, bloated and ineffective data platforms. **LSCP** and **Data Blueprint** understand the questions that need to be asked and how to build the right data platform or optimize an existing one to solve your most important data business needs.

LSCP+ DATA PLATFORM EXPERTISE

Authoritative Data Platforms for Business Entities – Customers, Product Information, etc.

- All other data platforms are negatively impacted if you do not store and manage your key business entity data effectively. This suggests highly structured and closely governed data repositories. Master Data Management (MDM) is a superb approach

Taxonomies, Ontology and Metadata Platforms

- These approaches are used in conjunction with other data platforms to provide greater business context to your data. This is especially important for any type of unstructured information such as documents. They will help reach a greatly improved performance for content search

Data Warehouses, Data Vaults and Data Marts

- These approaches provide a more structured and analytical approach to data platforms. Business questions and data sources are much better defined. They can support a wide range of business information and reporting needs

Big Data and Predictive Analytics Data Platforms

- This is not your typical IT project. These data platforms enable the exploratory functions for finding new insights. They are less structured, help identify trends and are not necessarily focused on precision

Operational Data Stores

- This approach offers a highly structured data platform, often capturing data in real-time. They are typically used to support operational processing and do not maintain long-term historical data

WHAT MAKES THE LSCP+ DATA PLATFORM APPROACH DIFFERENT

We build what you need

All data platforms are not the same. Customer and product information (e.g. "Master Data") needs a different data platform than does an analytical data warehouse, which is different still from a transactional-based data platform. We know these differences and how to design and build the data platform that best fits your needs.

We engineer, not just develop, data-centric systems

Our approach to building a data platform involves more than just writing some code. We understand that data platform stability and scalability are critical requirements for your

organization. Our data engineering approach includes building to satisfy these broader objectives and, in the end, delivers a higher return on your investment.

7 Business Intelligence (BI) – Data assets can increase revenue when used strategically with an optimal analytics infrastructure

- Have you struggled to effectively implement your BI suite of tools?
- Do your BI reports take a long time to run and then produce inconsistent results?
- Do your BI dash board solutions create sensory overload without yielding meaningful insights into your organization's daily operations?
- Do BI users extract data out of the relevant tools to use it to create their own shadow reporting systems?
- Do you use Big Data tools to get closer to Patients, to better understand their needs better by applying BI?

Ultimately for data assets to generate monetary value, business users need access to trust-worthy information when they need it and for whatever business purpose they have. Good BI and analytics is the intersection where relevant, timely information and raw business intuition come together. BI and analytics is where the business value of data is first visualized and then realized.

LSCP+ BUSINESS INTELLIGENCE EXPERTISE

Defining your BI and Analytics Requirements

- We define the questions the business users need to answer – the business context – beyond ERP!
- We understand how BI and analytics supports the user business processes – make the output actionable
- We present the output intuitively – data visualization matters

Building Dash Boarding / BI Reporting Infrastructures

- We develop the data models to support the BI and analytical requirements
- We develop the metadata to standardize the business meaning of your data assets
- We build and populate the integrated data repository to be used by your BI and analytical tools

User Adoption and Training – Part of the Change Management Process

- We develop and deliver end-user training on the use of business intelligence and analytical tools
- We develop and deliver end-user education on leveraging data more effectively

- We develop on-going production support plans to ensure data is updated and maintained

WHAT MAKES THE **LSCP+** BI APPROACH DIFFERENT

We build what you need

All business intelligence solutions are not the same. Different vendor's business intelligence software tools have varied strengths and weaknesses. We know them and their strengths and weaknesses. Furthermore, we know how to design and build business intelligence infrastructures that will effectively leverage your data platform investments and that will best fit your needs.

We engineer, not just develop, data-centric systems

Our approach to building business intelligence infrastructures involves more than just writing some code. We understand that business intelligence platform stability and scalability are critical requirements for your organization. Our data engineering approach includes building for the broader business intelligence objectives and in the end, delivers a higher return on investment.

AND WHEREVER TECHNOLOGY IS THE ENABLER

We recommend and use leading technologies

We do not have any preferences with regard to the technology used to develop your data platforms and BI infrastructure. We can assess and recommend the best technology tools to use based on your specific requirements. We have broad experience with many cutting edge technologies and understand that your data platform and BI infrastructure must integrate with your existing technology environment and organizational skill sets.

8   WHY DO WE QUALIFY?

The Partners to this initiative ideally complement each other;

LSCP – Delivers more business knowledge and greater process methodology outcome

Founded as a global professional network in March 2003 (privately owned) to provide expert consulting services to **Global Life Sciences** (Pharma, Biotech, Generics, Consumer, Medical Devices and eHealth):

- *Vision/Strategy* (V&S) for Enterprise Information (Content), driven by ISO and the International Conference on Harmonization (HL7; ISO IDMP, SPL & ICSR; [ICH] eCTD, CDISC, RPS) applied **Standards** and regional regulations (FDA; PDMA, EMA), in the context of the eCTD & Market Communication Competence Center. This delivers benefits, not just a burden of a Proof-of-Value (PoV) approach!

- ***Enterprise*** *(Information)* ***Data Governance*** *(EDG), with our Partner* **Data Blueprint** *an Architecture aiming for consistency, transparency, effectiveness and interoperability. We consider your needs for mobility and the shift to the "outside world" - including Web archiving, Social Media & Records Management (Proof of Evidence)*
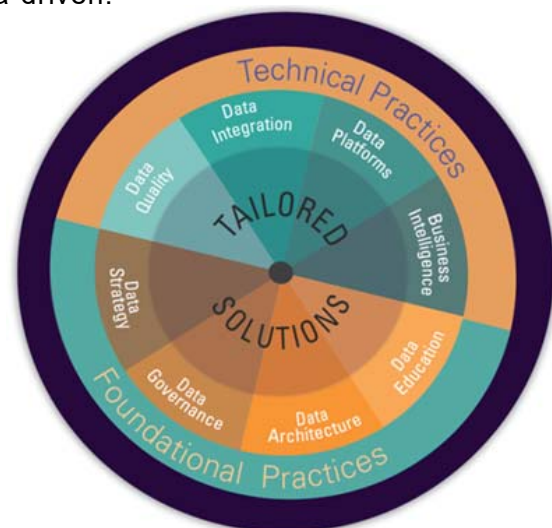
We cover any type of Content Submission (from within a Regulatory Information Management [RIM] system, including full **IDMP+**) & Communication Strategies. We consider XML Structured Content Authoring (SCA) that can enable the re-use and re-purposing of content for eCTD. We also consider overall communications for multiple audiences and applying Semantic Technologies to increase business effectiveness.

Data Blueprint – more methodology and technical

A specialized data management consulting firm that puts organizations on the right path to leverage data for competitive advantage and operational efficiency. We unlock business value. It is our belief that strong data management capabilities are the key to sustained long-term value creation. Our unique approach leverages core competencies in both foundational and technical data management practices. We help clients **leverage data** as a strategic investment and become data-driven.

OUR MUTUAL OFFERINGS

Our offerings are based on the guiding principles of developing a strong data management foundation before attempting to build systems and analytical platforms. The technical solutions can only be sustained over time if you take this approach. Therefore, we segment our offerings into Foundational Practices and Technical Practices as demonstrated in the graphic to the right.

OUR GUIDING VALUES

We strive to live our values in all of our interactions and engagements. You can count on us to be:
- *Honest*: We will give you the unbridled truth regarding your data and a roadmap to move forward.
- *Collaborative*: We want you to think of our team as an extension of your own throughout and after the engagement.
- *Insightful*: We rely on our experience, knowledge, and ability to understand with our Partner **LSCP** your organization in order to provide optimal solutions.
- *Driven*: We work patiently and persistently with selfless dedication, focused on the outcome and goals of our clients, company, and individual growth.

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