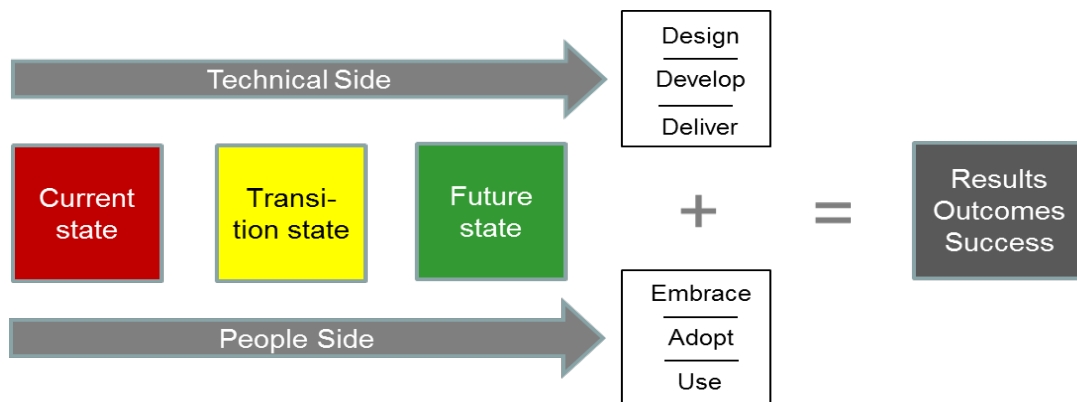


And once you have defined your new holistic PI Framework, you should think of this:

CHANGE MANAGEMENT (CM – SME Kathy Hagen)

The People Part of a Project:

The transition to implementing IDMP+ and EDG requires that everyone involved is aware of, accepts and acts on the change. Without people engagement, the work will achieve limited value.



Source: Prosci

LSCP has a deep understanding of CM and all of the critical aspects including Communication, Organizational/Cultural Change, Effective/Targeted Training and Leadership Alignment

Our CM process and tools are integrated throughout the project and our communication planning will be integral at every step of the way. We will partner with you to create a Change and Communication Strategy to ensure sustainable success of this crucial work

CM Enhances Sustainable Success and is crucial as you transitions to an Enterprise Data Platform



The CM Process ensures the people side of the return on investment is achieved.

LSCP believes CM is integral to project success: Therefore, the CM process is integrated in every step of the project and the CM Lead is part of the **LSCP** Leadership Team. Our team has implemented successful Change and Communication Strategies for numerous large scale initiatives and we will apply that expertise to assist you in engaging the various stakeholder groups to implement and adapt to the changes required, as well as receive the business benefits presented.

In a first phase of your project we will focus on the partnership with stakeholders (CM, Communications, Training, HR and Talent Management) on the first two steps; to assess the culture, organizational change readiness and impact, communications channels, and training environment to create a targeted, effective overall CM concept, strategy and CM Roadmap.

To close,

Our Contribution/Objective

- We do understand that your company is, as to IDMP already “in full swing”! Is your initiative holistically under way, including SPL & ICSR, referencing the ISO IG?
 - **LSCP** is probably one of the few Service Providers in this space with a **HOLISTIC** approach to **IDMP+** in conjunction with **Enterprise Data Governance (EDG)** and the application of **Semantic Technologies (ST)** – aiming to leverage your current/past investments in the topic or part of it
 - We would like to **COMPLEMENT** existing initiatives (integrate with current providers – non-disruptive!) and **not to replace them!**
- *Thanks for considering this message from this perspective*

AND ...

*What is your **CONCLUSION** here ...?*

LSCP would like encouraging you to get in touch with us at your earliest convenience:

We suggest to mutually discussing with your IDMP+ Stakeholders and our leading functional SMEs: Design and potentially execution of a Workshop to elaborate together an optimal, pragmatic approach defining about how to create and manage your **data assets** in the future. Benefit from the given synergies of the three key and crucial domains outlined above - high level to start with!

Collectively, we thank you for your attention ... and action!



- **Vada Perkins (US) MSc, BSN, RN** is a recognized international expert for the suite of ISO Identification of Medicinal Products (IDMP) standards as he is the topic leader in this initiative within ISO Technical Committee 215/Working Group 6-Health Informatics: Medicines and Pharmacy Business. During his tenure at the U.S. FDA, Vada worked closely with senior leadership on a broad range of regulatory and policy issues in the development, interpretation, and implementation of guidance, regulations, and international data standards (e.g., ISO IDMP, HL7 SPL, eCTD/RPS, ICSR, UDI) to support the comprehensive review of drugs, biologics, and devices throughout the product lifecycle. Vada brings along **EDG** experience within a major Health Authority. He is also a Managing Principle at IDENTIFICA, LLC.



- **Peter Aiken, (US) PhD, EDG** lead. Peter Aiken is acknowledged to be a top data management (DM) authority. As a practicing data consultant, author and researcher, he has been actively performing and studying DM for more than 30 years. His expertise has been sought by some of the world's most important organizations and his achievements have been recognized internationally. He has held leadership positions, consulted with more than 75 organizations in 21 countries across numerous industries, incl. defense, banking, healthcare, telecommunications & manufacturing. Sought-after keynote speaker and author of multiple publications, incl. his latest the "Case for the CDO" & "Monetizing Data Management". He hosts the longest running and most successful webinar dedicated to DM (hosted by Dataversity.net). Peter is the Founding Director of Data Blueprint, a consulting firm that helps organizations leverage data for competitive advantage & operational efficiencies. He is also Associate Professor of Information Systems at Virginia Commonwealth University (VCU), past President of the International Data Management Association (DAMA-I) and Associate Director of the MIT International Society of Chief Data Officers.



- **Ruedi F. Blattmann, (CH)**, Managing Partner of the **LSCP** global network, Ruedi is recognized for thought leadership on implications of eCTD, ISO IDMP & ISCR(R3) in a *Holistic Vision & Strategy (V&S) from an EDG perspective*: Focusing on flow of information in collaboration and process outcome, optimal transparency, consistent content re-use opportunities, developing business benefits while maintaining compliance, e.g. in Pharmacovigilance (PV); Knowledge Management (KM) – semantically enriched/enabled concepts for "discovery in context" in the LS market space and beyond, focusing on Enterprise Structured Content Authoring & -Management, Change Management (CM), Compliance dimensions, RM. An active member in the Swiss eHealth scene with all stakeholders, incl. Health Insurer.



- **Kathy L. Hagen, (US)** Partner, SME CM/KM. Extensive Academic & Industry experience. Organizations are experiencing large scale risk from worker retirements, globalization, multi-generations in the workforce, mergers and acquisitions and regulatory/legislative changes. Kathy Hagen is an expert in Critical Knowledge Transfer and Change Management (CM) programs, helping clients reduce risk, retain business critical knowledge and ensure employee and leadership engagement in all types of transitions. The KM Strategies, Knowledge Transfer methodologies and CM/Change Leadership programs developed by Ms. Hagen have been successfully implemented in companies around the world, used extensively by organizations facing the challenges of a transitioning workforce, those needing to quickly and effectively transfer business critical knowledge to a diverse workforce

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