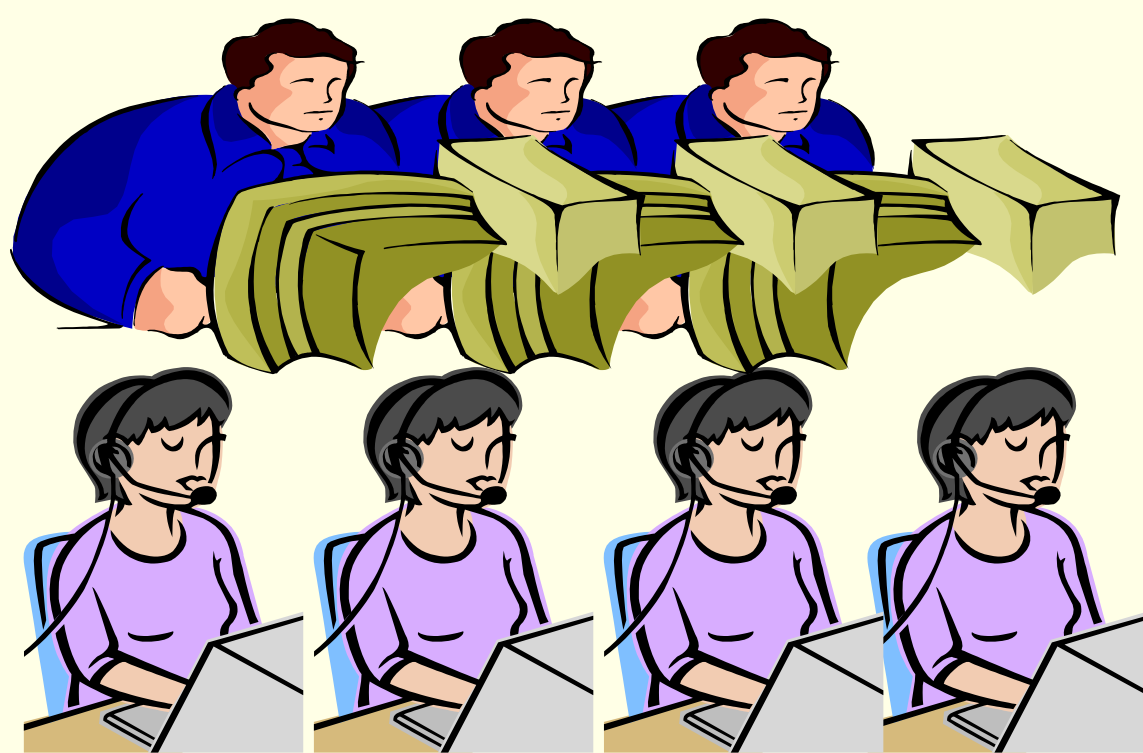


Comparing SDTM Software Solutions

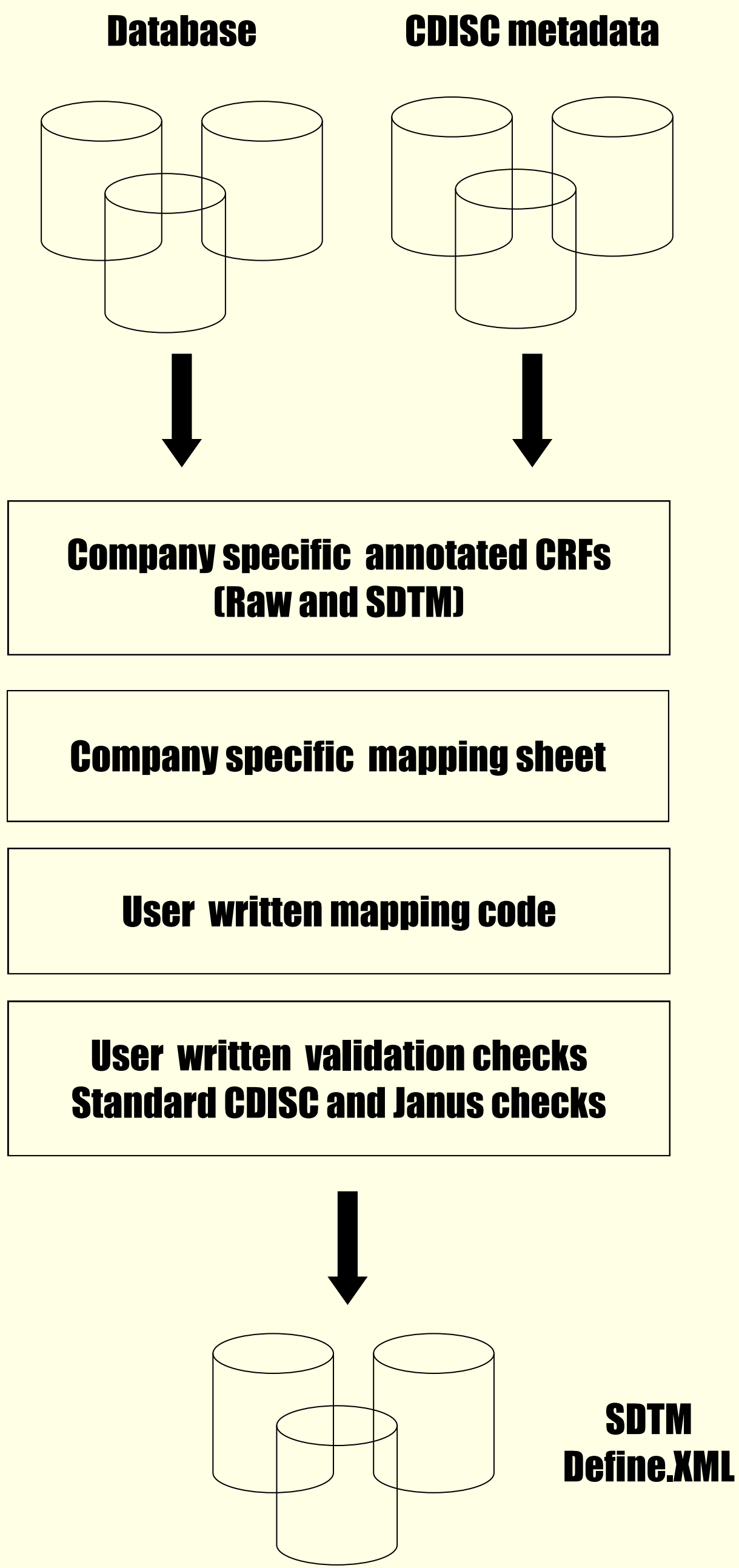
Michael Wall, Programming Director, Phastar



Experienced SAS Programmers, Existing Software, Straightforward Solution



- ♦ Large resource pool, likely to be existing staff
- ♦ Extensive pharma knowledge
- ♦ Extensie SAS knowledge
- ♦ Limited other software expertise
- ♦ Limited experience of new tools
- ♦ Limited formal life-cycle experience



Benefits:

1. Easy to resource
2. Little additional training
3. Can be maintained by new or existing staff. Existing staff may buy-in to the solution as they are involved in system development
4. If key developers leave then they can be replaced
5. If developed using Base SAS then it is likely the customer can use their existing license.

Risks:

1. Sub-optimal performance
2. Traceability questionable
3. Life Cycle must be managed appropriately. A lack of SDLC knowledge could cause a significant risk of failure.

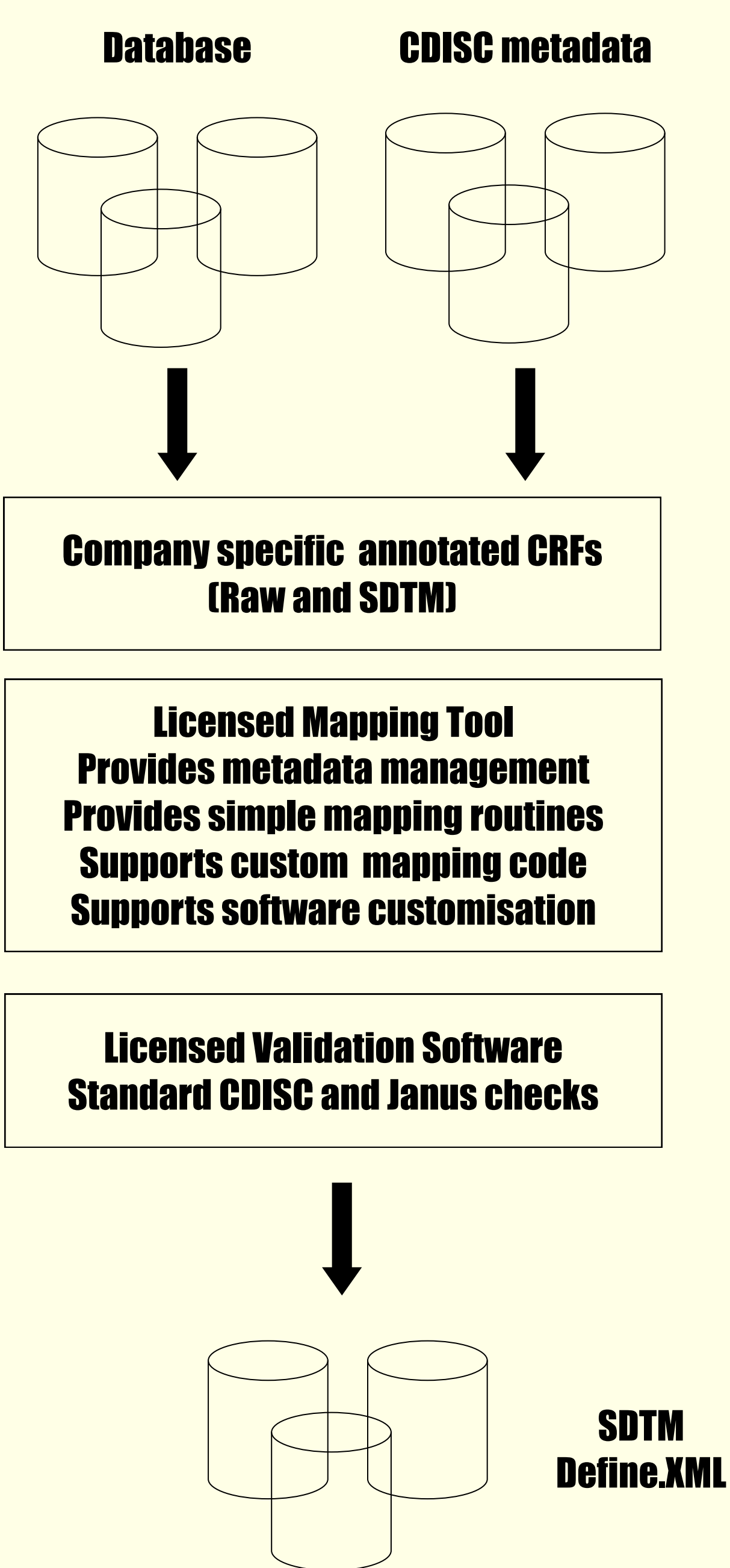
Costs:

1. Low development time. Can be easily developed in phases
2. Medium developer costs
3. Low software costs. Can use some existing licenses
4. No additional hardware
5. Additional development costs as the CDISC requirements change

Expert Developers, Latest Technology, Complex Solution



- ♦ Very small resource pool, unlikely to be existing staff
- ♦ Extensive pharma knowledge
- ♦ Extensive SAS knowledge
- ♦ Extensive other software knowledge
- ♦ Extensive experience of new tools
- ♦ Extensive formal life-cycle experience



Benefits:

1. If successful, provides a near optimal solution
2. Good traceability
3. Vendors provide software updates, advancing the system at little development cost

Risks:

1. Complexity of solution
2. Staff retention. It is easy to recruit expert developers to develop new, latest solution software. It is difficult to retain these staff when the system enters the testing and maintenance phases.
3. If appropriate resource cannot be maintained for the life of the system then this can lead to system failure
4. Existing staff may not buy-in to the solution easily.

Costs:

1. High development time. An interim solution may be required.
2. High developer costs
3. High software costs - likely to be a cost for the life of the solution
4. Additional hardware costs may be required
5. High cost of maintenance
6. Many costs are ongoing

Introduction:

Numerous solutions are available for creating SDTM data, ranging from in-house SAS solutions through to the latest commercial products. In order to select the most appropriate we must perform a careful risk-benefit assessment. Here we highlight some critical factors that should be considered when making this selection.

The 2 Extremes:

In this poster two approaches for SDTM software solutions have been illustrated. The first is a straightforward approach where the existing workforce have used existing software. This is a typical in-house solution. The second is extensive software development . This involves identifying the most appropriate software, recruiting a team of experts, and customizing this to provide an optimal solution.

Shared Processes:

Many of the business processes are common across the solutions. For example, both require the creation of annotated CRFs (or equivalent) of the Raw and SDTM data. The most complex mappings will require experienced Pharma Programmers to write the mapping code, irrespective of the solution selected. In this poster, the first extreme would require SAS programmers to write base SAS code whilst the second extreme could require development of SAS code in a mapping tool, or it could require development of a Java Add-In that writes mapping code.

Using Mapping Tools:

Much of the licensed software available provides an ability to create Raw to SDTM mapping programs using wizards. We should carefully evaluate the added-value of these solutions. Are we using wizards to automate the obvious? If the wizards are producing complex code, then how complex is the code it writes, how would we customize this code, and how complex would the wizard need to be to handle all scenarios?

Considerations:

When evaluating a solution, careful consideration must be given to a number of factors:

- ♦ Development costs increase with complexity. However, by purchasing a software solution the vendor should provide enhancements.
- ♦ Software/Hardware costs increase with complexity and typically last for the lifetime of the system
- ♦ Maintenance costs. A complex solution requires retention of skilled staff, which becomes difficult when the development phase ends. This significant risk is often overlooked and frequently leads to system failure and retirement. This may be resolved by entering into an agrrement with a vendor, but these agreements can be expensive.
- ♦ Development time. As complexity increases, so do timelines and this raises the likelihood of a requirement for an interim solution.
- ♦ Expected lifetime. The straightforward SAS solution illustrated in this poster does not provide an optimal solution. But through company-wide implementation of CDISC standards, mapping efforts should reduce over time. Successful implementation of these standards would make the mapping of standard data trivial, and would simplify the mapping of even complex non-standard data.
- ♦ Care should be taken not to over-invest in solutions that may eventually perform trivial mapping tasks.

Conclusion:

It is recognised that the optimal solution for delivering SDTM data involves implementation of CDISC standards early in the data collection process. For example, standards at Protocol and CRF level obviously reduce the mapping workload. If a company embraces these standards then the necessity for a complex, customised SDTM solution reduces.