

Outsourcing SEND Conversions A Case Study

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Standard for Exchange of Non-clinical Data (SEND)

Data standard developed by CDISC - Clinical Data Interchange Standards Consortium

- Study Data Reviewers Guide DRAFT.pdf
- Study Data Reviewers Guide DRAFT.docx
- bw.xpt
- cl.xpt
- co.xpt
- dd.xpt
- dm.xpt
- ds.xpt
- ex.xpt
- fw.xpt
- lb.xpt
- ma.xpt
- mi.xpt
- om.xpt
- pc.xpt
- pooldef.xpt
- pp.xpt
- relrec.xpt
- se.xpt
- suppcl.xpt
- suppma.xpt
- suppmi.xpt
- supptf.xpt
- ta.xpt
- te.xpt
- tf.xpt
- ts.xpt
- tx.xpt
- define.xml
- define1-0-0.xsl



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Standard for Exchange of Non-clinical Data (SEND)

Specifies a way to present non-clinical data in a standard way

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Standard for Exchange of Non-clinical Data (SEND)

Required by FDA as part of a submission for drug approval

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Benefits of SEND in the Drug Approval Process

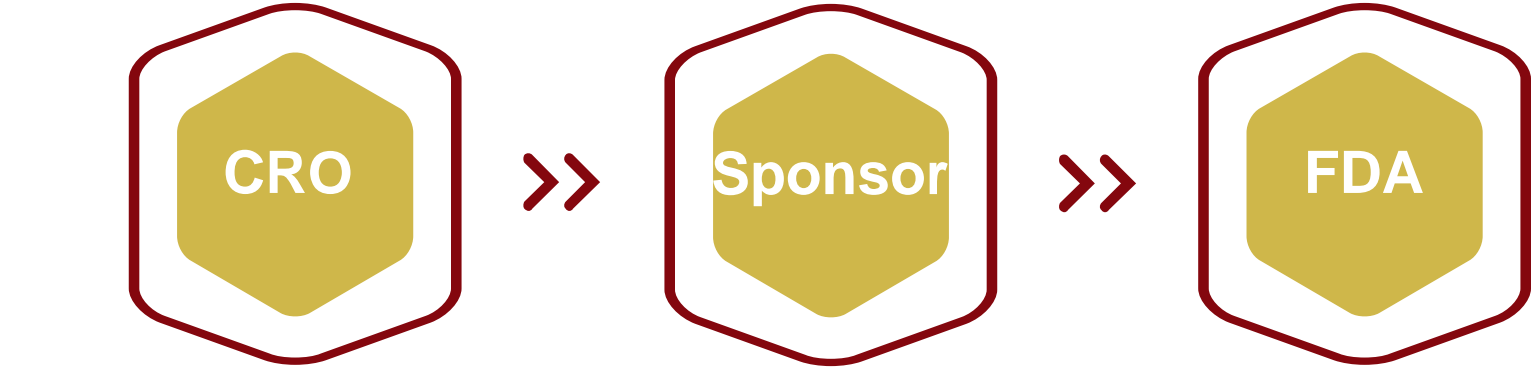


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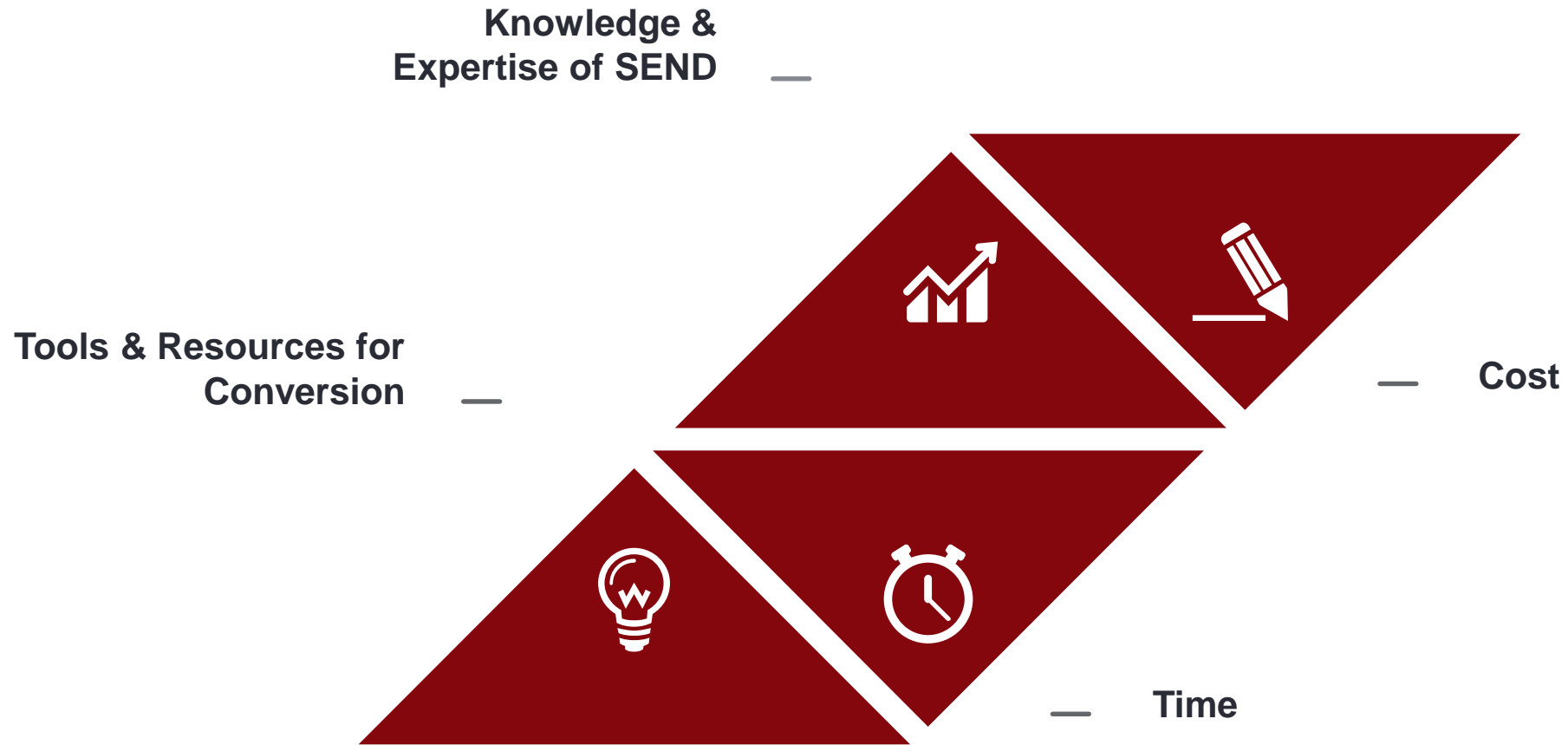


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Converting Non-Clinical Data to SEND Format



Factors Influencing the Decision to Outsource



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WHO IS
ACCOUNTABLE



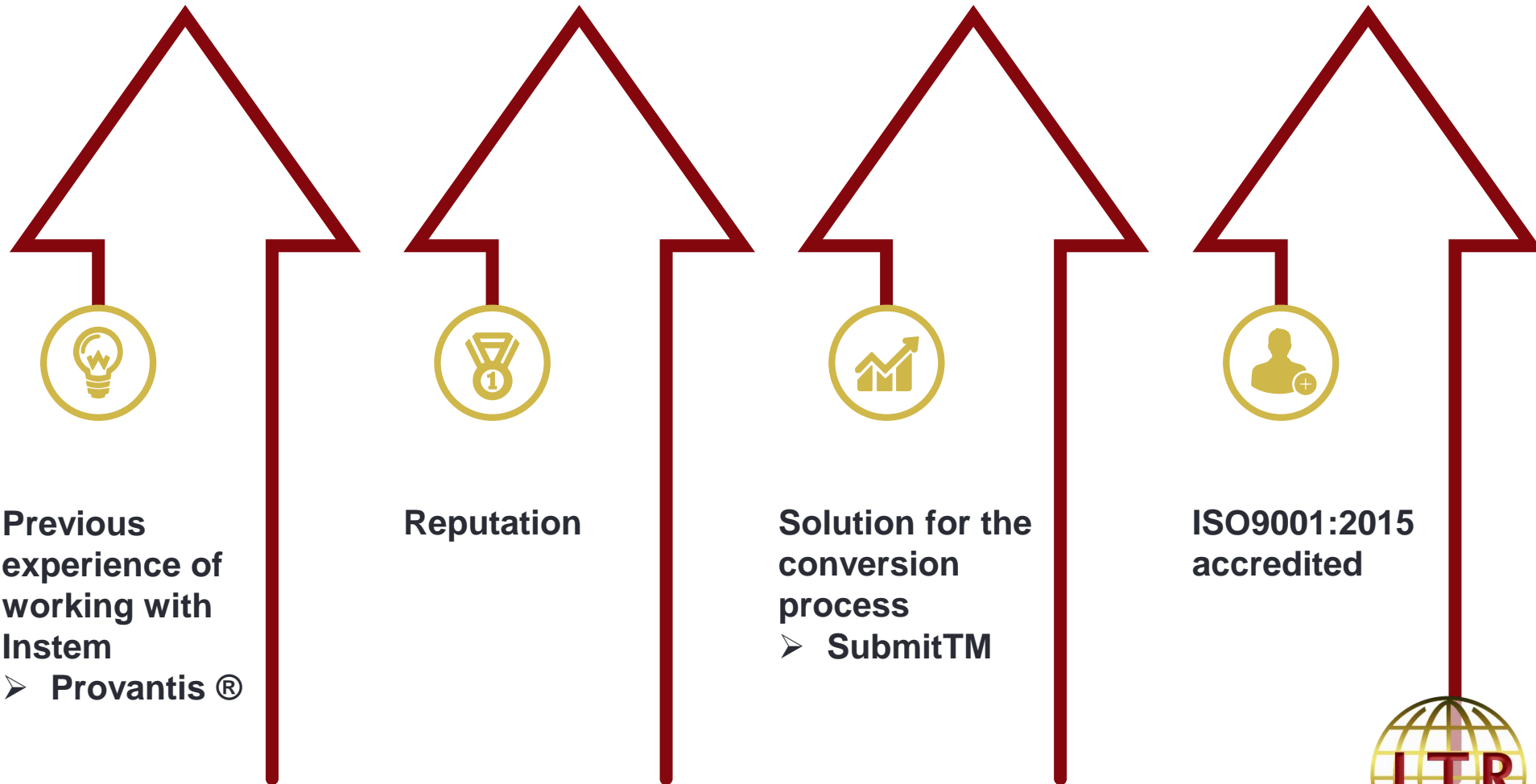
...for the fault
responsibility
at his new place



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Why ITR Selected Instem as the Service Provider



Key Dependencies



Data Integrity



**Data Security
Privacy**



**Expertise &
Knowledge**



Quality



Timeliness



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Qualification Process

Request for Information



Desktop Audit



Remote Audit

- Instem personnel
- Processes and procedures
- Review of documentation



Conducted a Pilot Conversion Study

- ITR's study data



Pilot SEND Conversion Study



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Quality Considerations



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Key Area Identified

Data hosted in a data warehouse owned by a third party

Risk



Mitigation

Evaluate controls in place to mitigate risks



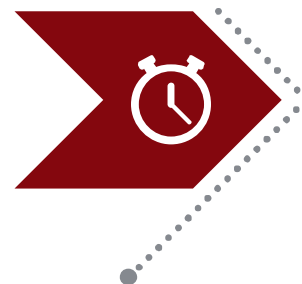
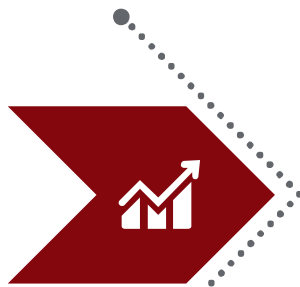
Going Live

Several Conversions Since

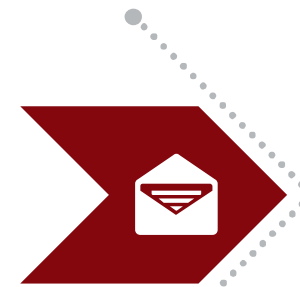
Continue to Assess Services



First Commercial
Conversion
November 2017



Increase in Demand



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Lessons Learned

Collaboration Is Key

Must Be Adaptable

Pilot Study a
Valuable Exercise

Not to Underestimate CRO
Time and Resources



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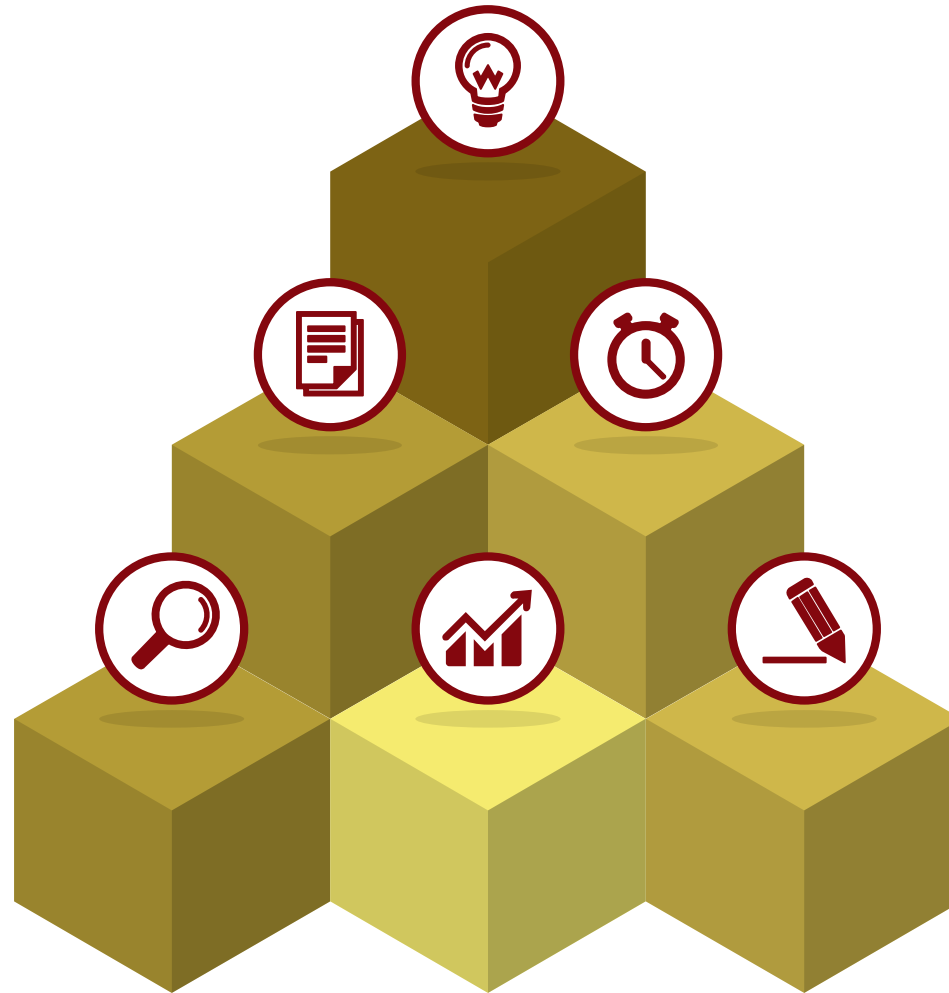
Future

Continue to Review & Improve Process —

— Collect data in a SEND Compliant Manner

Automate Data Capture —

— SEND Files a Valuable Tool
➤ Study Data Evaluation & Interpretation



Is Your Team SEND Ready?

Questions?



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