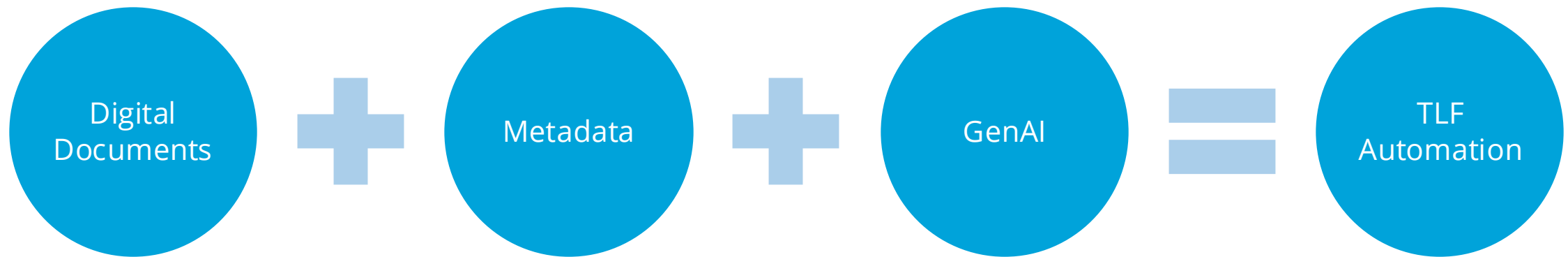


THE MAGICAL TRINITY OF TLF AUTOMATION

Alastair Scarlett, Instem

ML19

THE MAGICAL TRINITY OF TLF AUTOMATION



DIGITAL DOCUMENTS

- Transcelerate
 - CC&R
- SAP
 - Table Shells



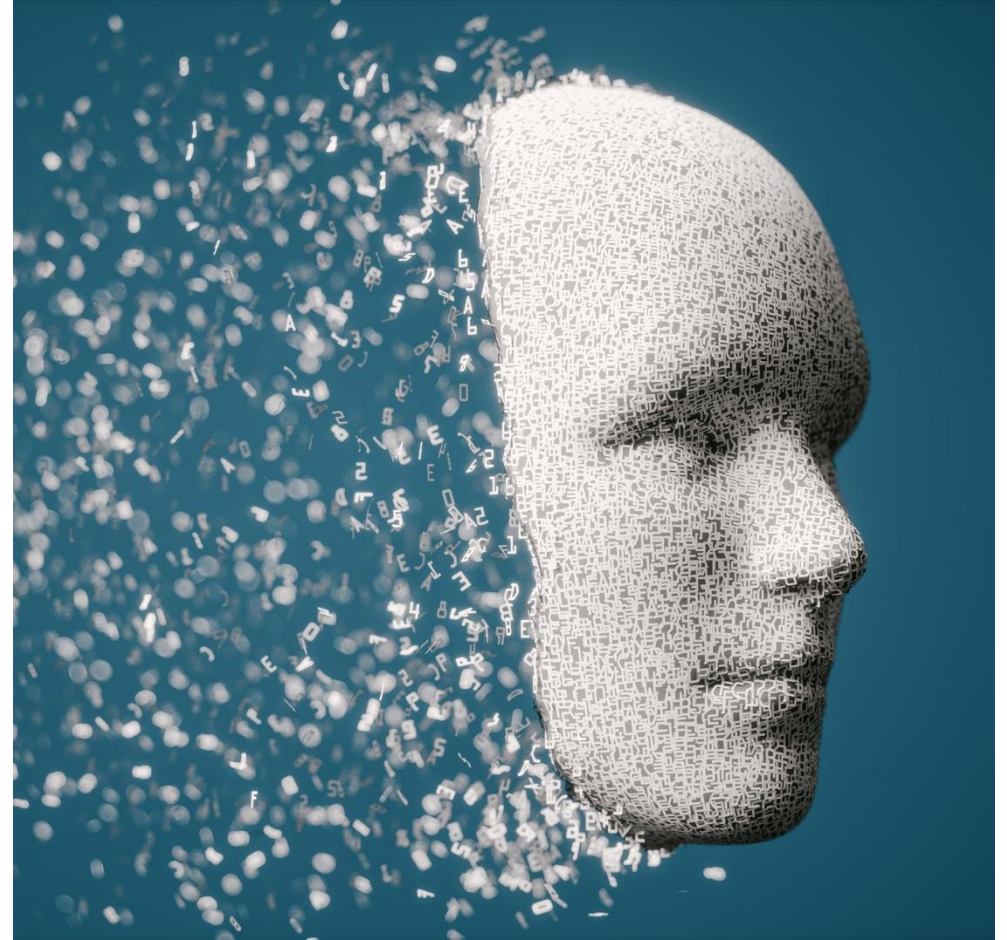
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  <Study>
    <StudyName>Study001</StudyName>
    <ProtocolName>Protocol001</ProtocolName>
  </Study>
  <Metadata>
    <Domain>DM</Domain>
    <Variable>DOMAIN</Variable>
    <Label>Domain Name</Label>
    <DataType>Text</DataType>
    <Length>50</Length>
    <Comment>The domain name for the dataset.</Comment>
  </Metadata>
  <ItemGroup>
    <ItemGroupName>Demographics</ItemGroupName>
    <Item>
      <ItemName>AGE</ItemName>
    </Item>
  </ItemGroup>
</StudyDefinition>
```

- CDISC
 - ADaM Standards
 - Define.xml

GEN AI

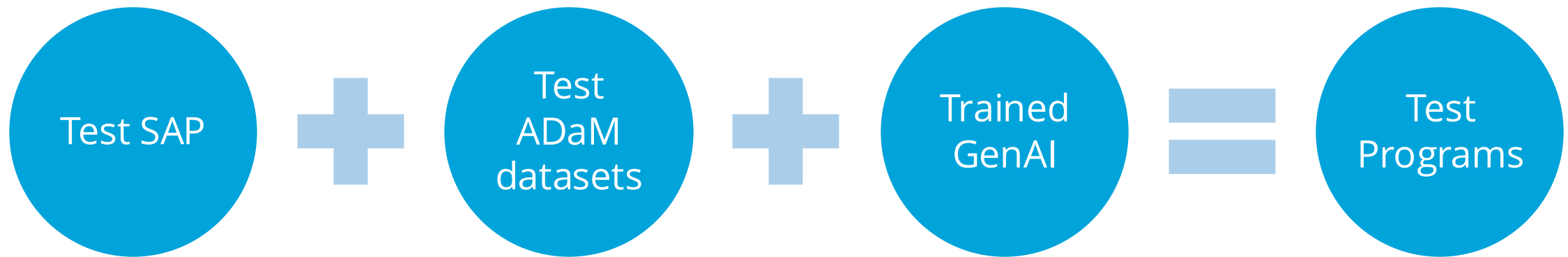
- Model Choice
- Language
- Training
- Regulatory Guidance



TRAINING YOUR AI MODEL



TESTING YOUR AI MODEL



SUMMARY

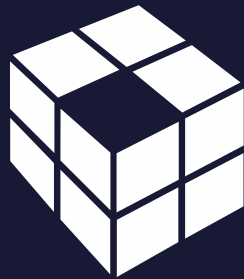
GenAI offers the possibility of automation of TLF programming with some caveats:

- Implement internally
- Training required
- Independent testing
- Consider Regulatory Agency advice

THANK YOU

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