Q3-Q4 RELEASES 1 & 2 Basic Word Edition and

Implementation Toolkit

Q2

RELEASE 4

- Alignment with NIH FDA Protocol Template
 - Libraries for pediatrics, TQT, Alzheimer's
 - Refinement of Technology-Enabled Edition

ONE CPT RELEASE

- Evaluate content for devices, statistical aspects, vaccines, CV-safety
 - Expand disclosure
 - Regulatory and CPT user-driven updates

The CPT
JOURNEY

2015 2016 2017

EXPAND AUTOMATION & REUSE

- Explore CPT content reuse in the SAP and CSR
- Improve library creation

2018 OUTLOOK

Q4

Successful proof of concept on automation of CRFs and traceability

RELEASE 5

- Enabled disclosure of protocol elements to CT.gov & EudraCT
- 5 new therapeutic area libraries

ENGAGEMENT

- Health Authority engagement
- CPT user community engagement
- Other TransCelerate BioPharma, Inc. initiative connections

GOVERNANCE

• Ensure the sustainability of the CPT

Q2 **RELEASE 3**

• Technology-Enabled Edition

 Added guidance for amendments