Going Global – 70% of Reuse with Structured Content

Accelerate your time-to-market

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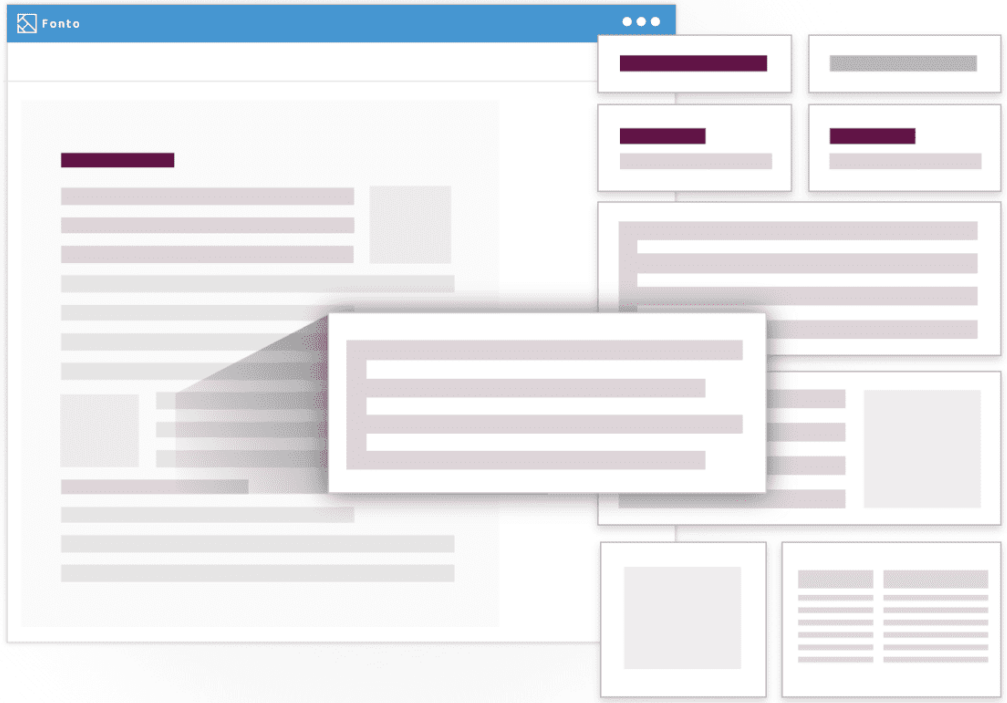
Agenda

- **Single source of truth** to ensure a neutral source is ready for submission to multiple agencies, such as EMA, FDA, etc.
- **Instantiation** of data, automatic table data instantiation with the ability to know when data is updated.
- **Global content** automating translation and localization
- **Informed Consent Form** use case of managing reuse from a global template to a country and site templates

Adoption of structured content components



Unstructured Content

Structured Content

Why create documents with structured content components?
Single source of truth

- Write once, reuse many times
- Semantically rich and interoperable
- Full audit trail – compliancy
- Unify collaboration, accuracy
- Output and translation automation

“The output Informed Consent would serve as the starting point of negotiations with sites. This activity has enormous value, including shortened submission timelines, reduced errors, and site friendliness.

Consistency and Quality: This system could solve many of our protocol amendment issues seen to date.”

Medical writer at a pharmaceutical company

Managing documents as structured components

A structured approach to content creation supports content reuse and data integration at scale, facilitates faster creation and review, reduces conflicts/variation, and diminishes the need for data integrity checks

Content components are tagged with metadata

Stored and managed in a Component Content Mgmt System

Component 1: Heading

Component 2: Paragraph

Component 3: Images

Component 4: Table

Component 5: Data

Components are used to author a document from a defined template

Content components are reused across templates and documents

Study procedures

Doc 1

Schedule of assessments

Doc 2

Adverse events

Doc 3

… and then approved and stored in Veeva

Vault

Collaborative authoring / review & versioning
Ability to generate output in Word / PDF / XML etc.

Component reuse within Informed Consent Templates

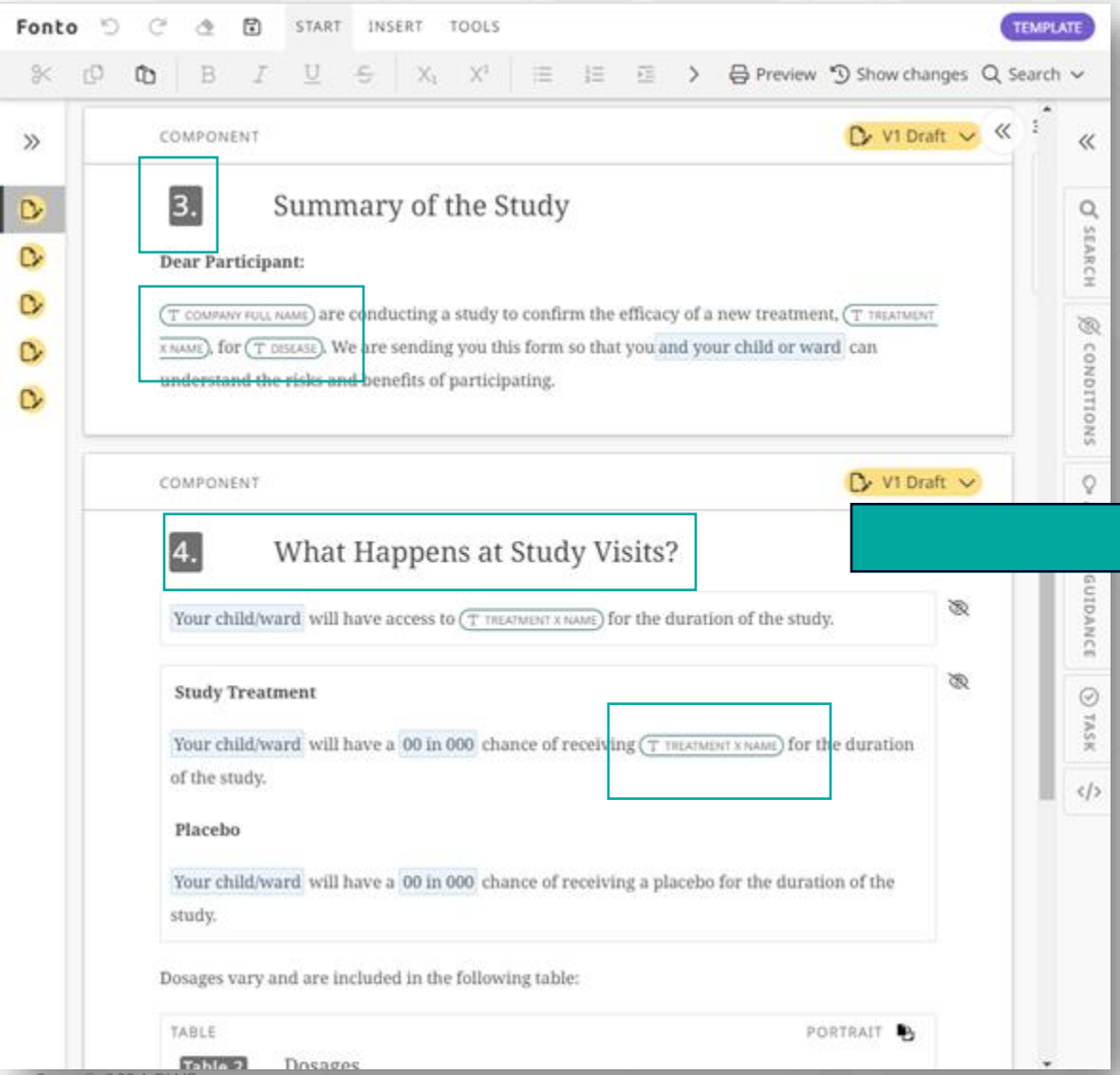
Global ICF Elements	Global ICF Template	Country/Site ICF Template
Global Cover Page	Global Cover Page	Country ICF Template Cover Page
Summary of the Study	Summary of the Study	Summary of the Study
Are there any benefits to me…	Are there any benefits to me…	Are there any benefits to me…
What happens at Study Visits?	What happens at Study Visits?	What happens at Study Visits?
	Signature Page	Country Signature Page
	Optional consent for activities…	Optional consent for activities…
	Optional consent for Additional…	Optional consent for Additional…

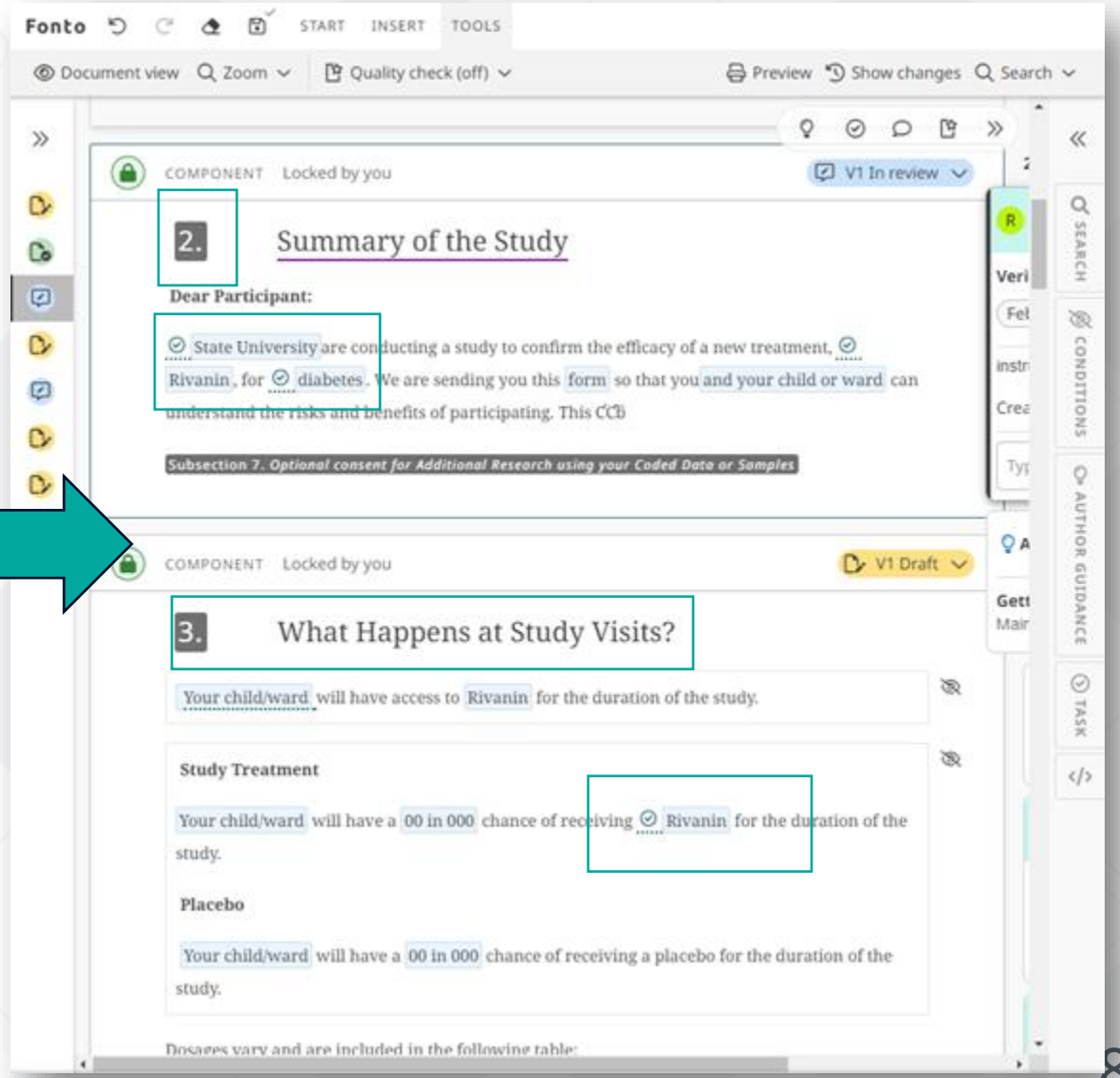
Component reuse (as-is)

Component reuse (derivative)

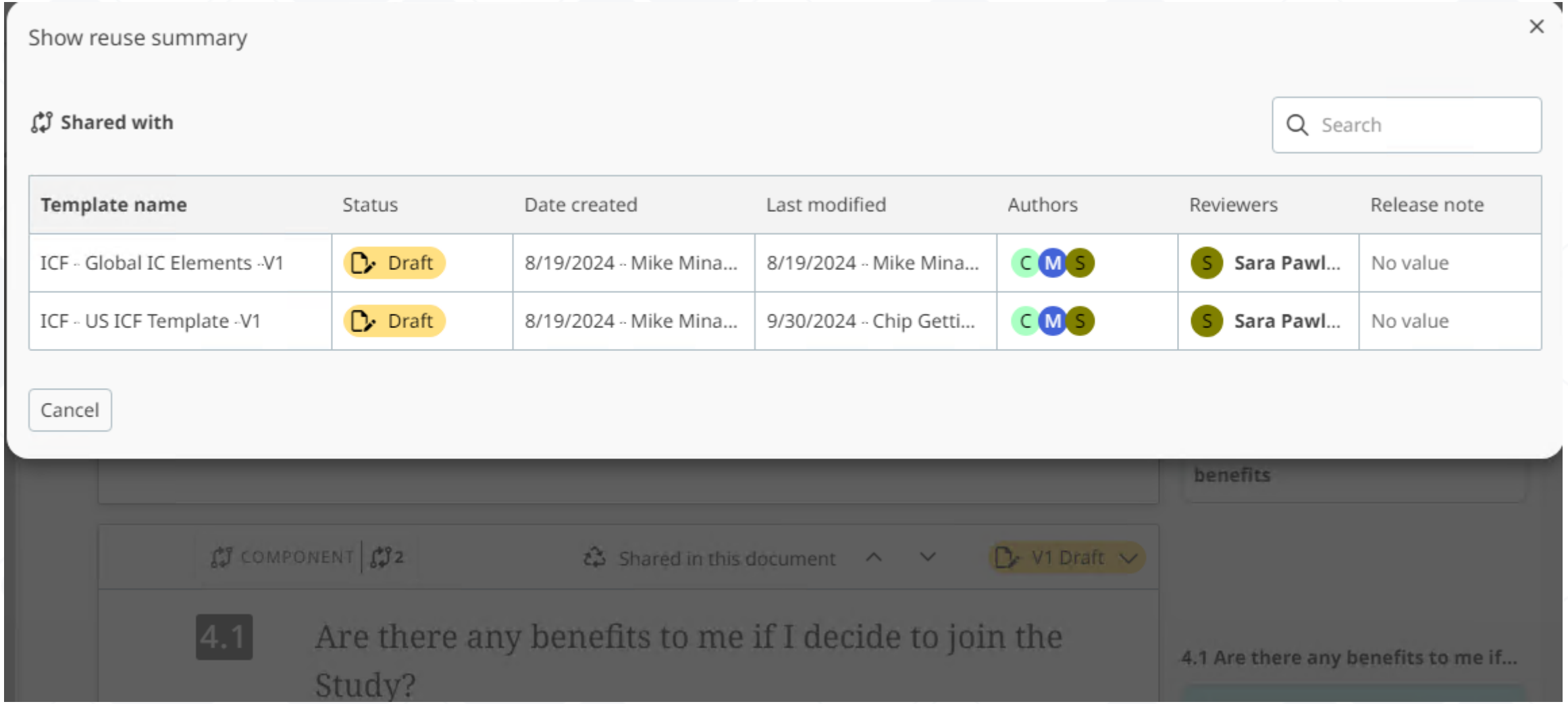
Informed Consent – Data-Driven Documents

Global IC Elements reused to generate Country IC





Powerful reuse reporting



From country-focused IC administration to…

- Responsibility at country level
- Inconsistent processes
- Administrative burden on clinicians
- No reuse of content or translation

Higher cost, slower pace, less control

Structured Component Content + Translation Management

- Global control
- Consistent processes
- Improved quality/reduced risk
- Minimize translation / lower costs

…Global Content and translation management

“It took me about five hours to redo the authoring of this section, considering all the tables and data content that is available. In contrast to this, usually, it would take me a minimum of 10 to 15 hours to complete the same work.”

Medical writer at a pharmaceutical company

“We release five new products to the market per year, and that number is growing. Per new drug application, our scientists spend 800 days on automatable work, i.e. collect, retype, change, insert and format content and data. We needed to speed up these processes and reduce the amount of costly manual work. That’s solved by Fonto IAP.”

Digital Transformation Program Lead at a pharmaceutical company

Thank you! Learn more

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Learn more on the advantages of structured content within pharmaceutical use cases

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