

AUTOMATED RTF TABLE TRANSLATION AN ILLUSTRATED APPROACH

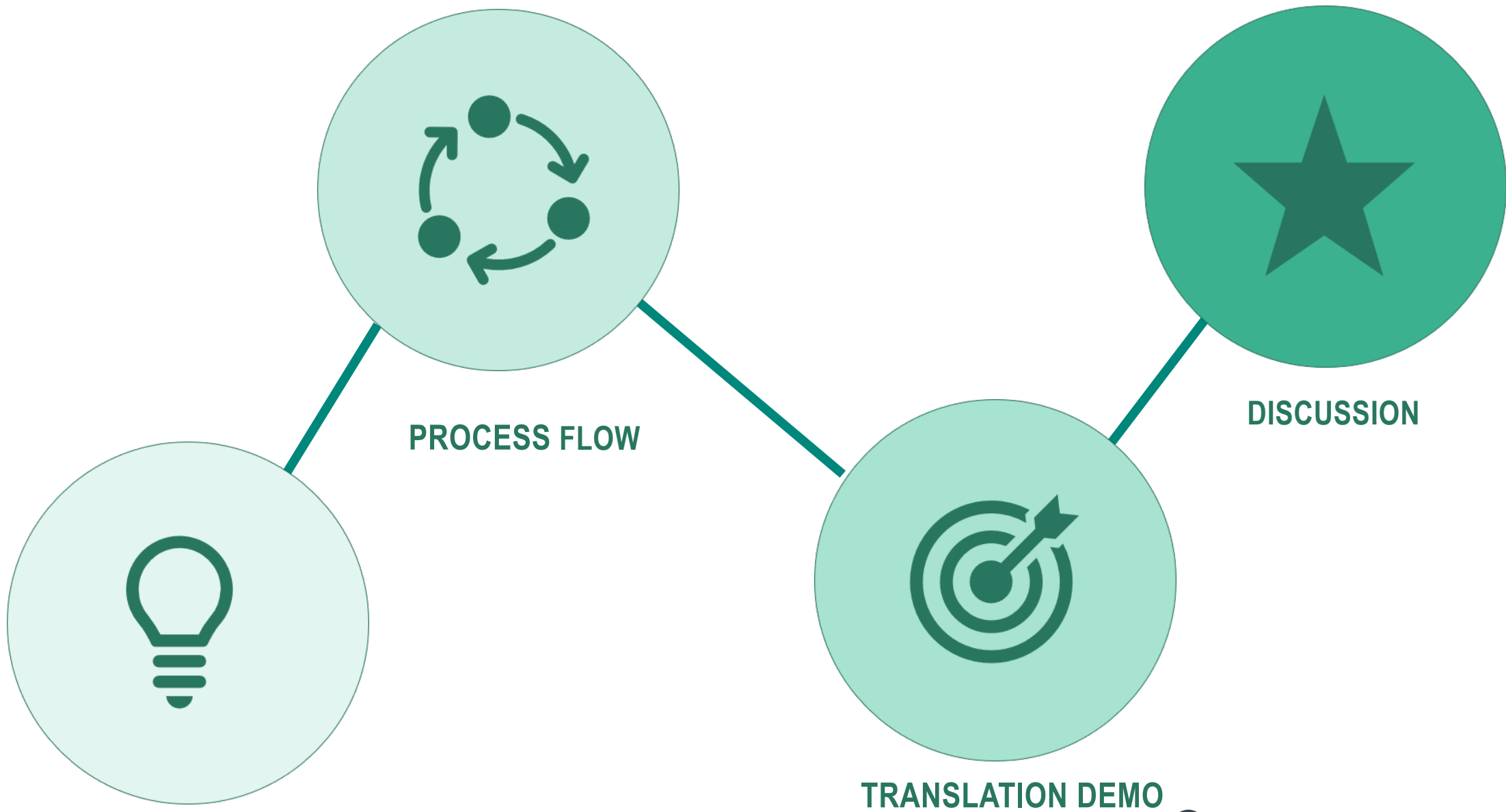


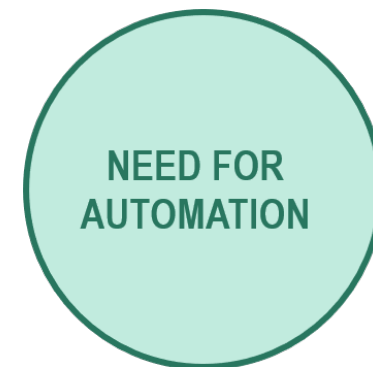
Date: November, 11 2019

Authors: Qian Wang

Amit Bhaniani

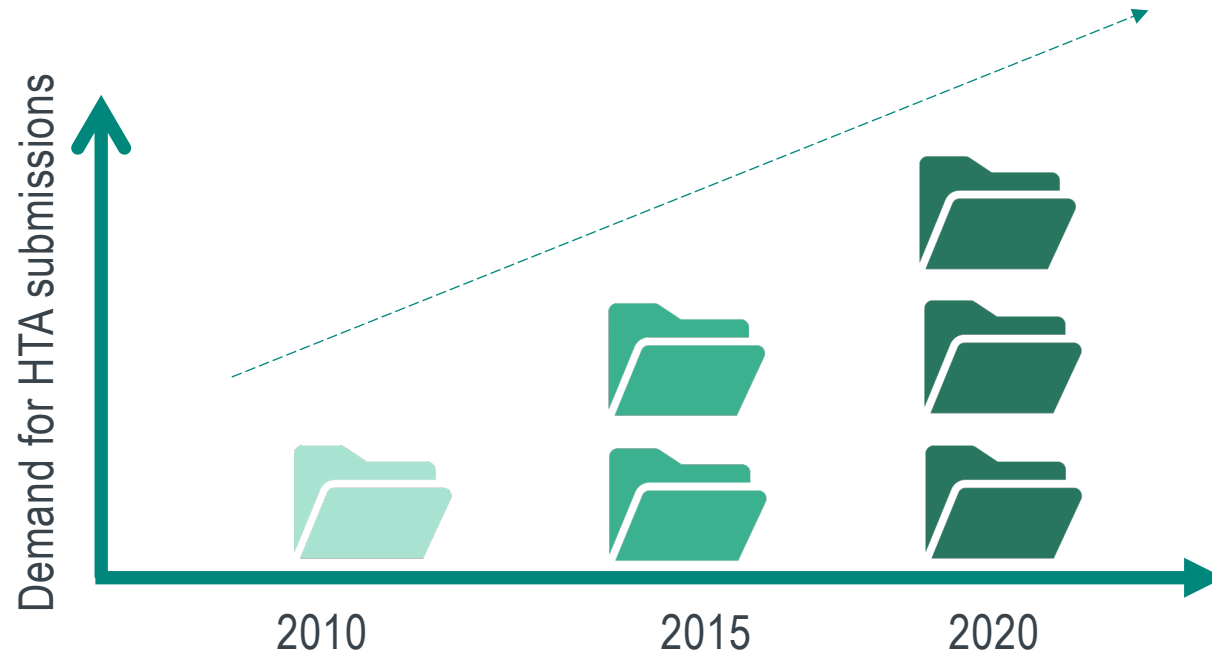
Carl Herremans





HTA Dossiers

- Local language is usually required for HTA dossiers and some regulatory submissions (e.g. China, Japan)
- Requests for HTA dossiers are on an increase
- ~1000s of tables are prepared in the authoring of HTA AMNOG dossiers



Need for Automation

Without Automation

Without automation, translation process requires manual copy of English output and replacement of English text and numbers with local language and formatting.

1. Manual replacement of English text, numbers and formatting with local language – **time intensive and prone to errors**
2. **Independent effort** across projects
3. **Inconsistent translation** of tables across projects
4. **Lacks traceability and reproducibility**

With Automation

1. Automatic translation of English tables to local language – **saves time and reduces errors**
2. Use of **standardised translation tools** based on centralised dictionary
3. **Consistent translation** of tables across projects
4. Inherent **traceability** and **reproducibility**

Existing Tools

Most commonly available translation tools:



Google Translate



Brand and product names are trademarks of their respective companies.



Readily available
Easy to use
Quick learning curve



Confidentiality and reproducibility
Control on exact terminology
Validation of the software
Backward compatibility





Existing Tools - sample

Analysen des Gesamtüberlebens
(Intention-to-Treat Population)

Studieren: ABC	Behandlung1			Behandlung2			Behandlung1 vs. Behandlung2	
	N	Patienten mit Ereignis n (%)	Mittlere Zeit in Monate [95 %-CI]	N	Patienten mit Ereignis n (%)	Mittlere Zeit in Monate [95 %-CI]	Hazard Ratio [95 %-CI]	p-Wert
Gesamtüberleben	154	44 (28.6)	4.4 [0.7; 7.7]	151	64 (42.4)	1.14 [0.4; 2.15]	0.60 [0.41; 0.89]	0.010
Gesamtüberleben - Angepasst	154	44 (28.6)	6.4 [4.2; 8.4]	151	46 (30.5)	0.75 [0.08; 1.13]	0.70 [0.46; 1.07]	0.101
Gesamtüberleben - RPSFT	154	44 (28.6)	7.2 [6.5; 8.1]	151	45 (29.8)	0.65 [0.60; 0.71]	0.57 [0.32; 0.86]	0.010

Datenbank-Cutoff-Datum: 31DEC2099
Anzahl der Patienten: Behandlungsabsicht

Decimal separator

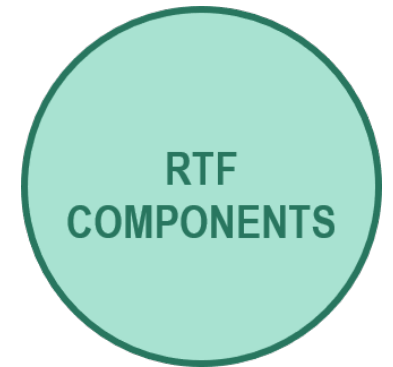
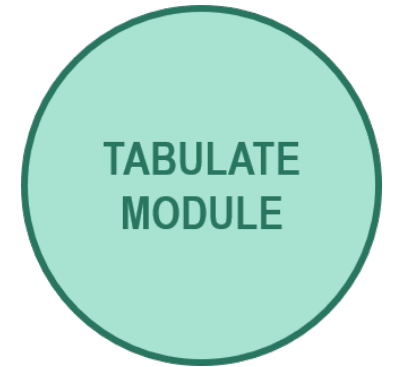
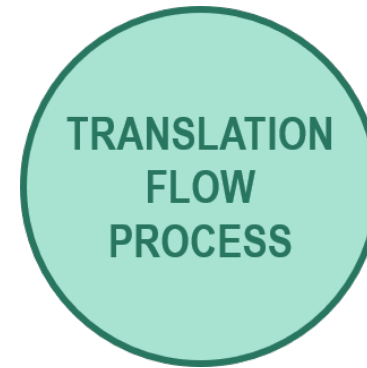
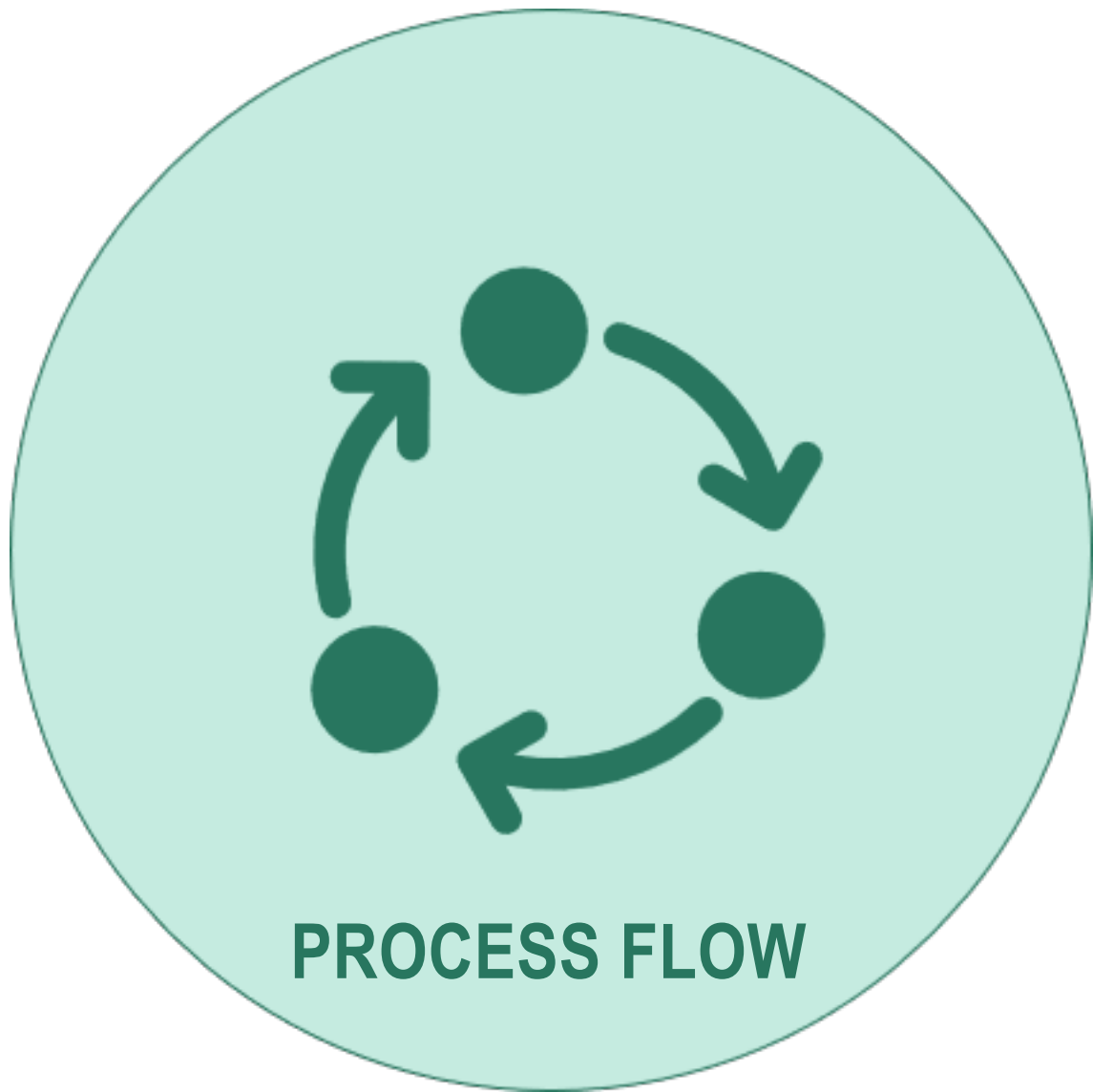
Expected Outcome

Analysen von Gesamtüberleben
(Intention-to-Treat Population)

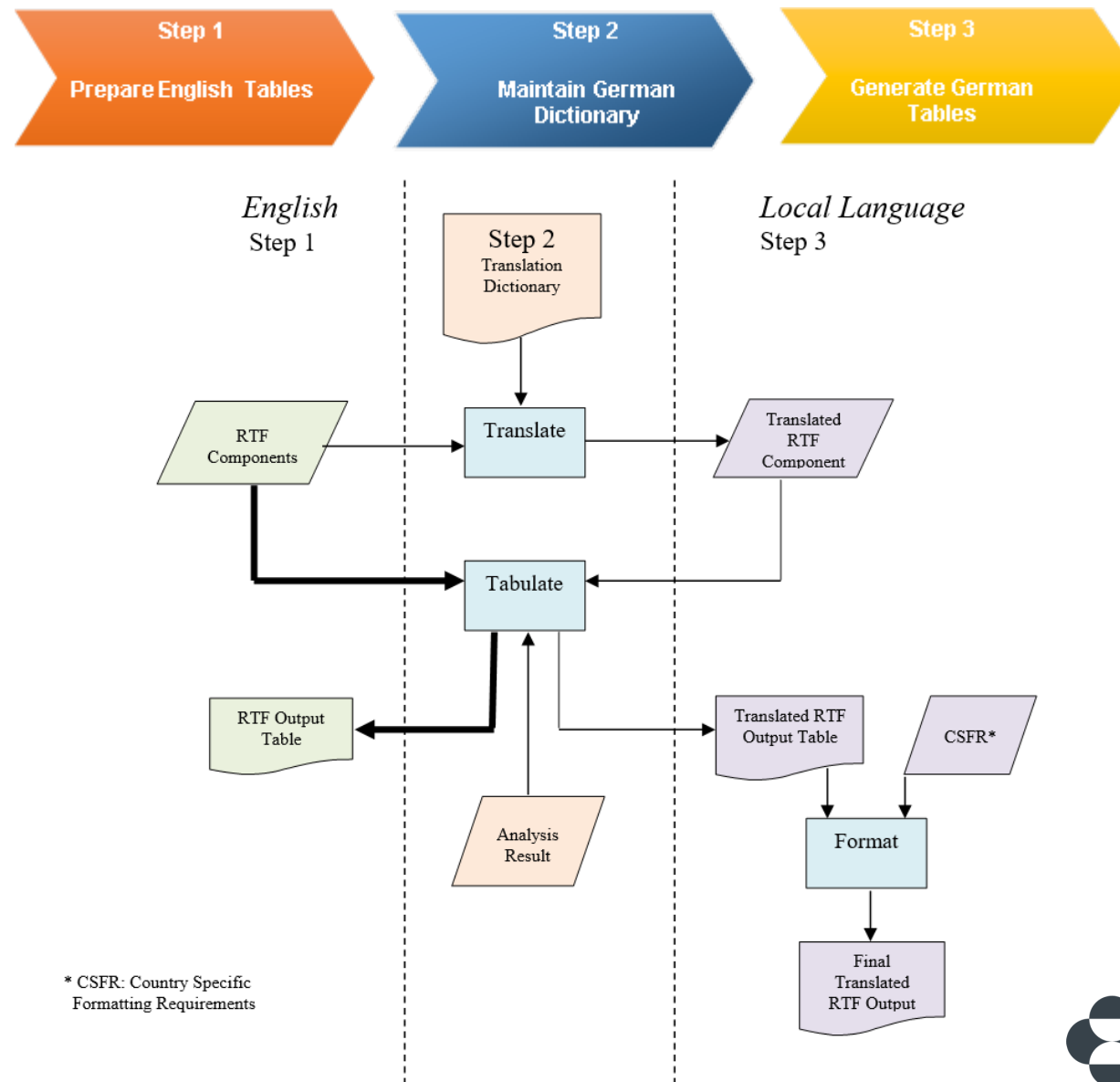
English to German is not available in
Systran translate

Studie: ABC	Behandlung1			Behandlung2			Behandlung1 vs. Behandlung2	
	N	Patienten mit Ereignis n (%)	Mediane Überlebenszeit in Monaten [95 %-KI]	N	Patienten mit Ereignis n (%)	Mediane Überlebenszeit in Monaten [95 %-KI]	Hazard Ratio [95 %-KI]	p-Wert
Gesamtüberleben	154	44 (28,6)	4,4 [0,7; 7,7]	151	64 (42,4)	1,14 [0,4; 2,15]	0,60 [0,41; 0,89]	0,010
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Datenschnitt: 31. Dec 2099
Anzahl der Patienten: Intention-to-treat



RTF table creation and translation flow process



Tabulate Module

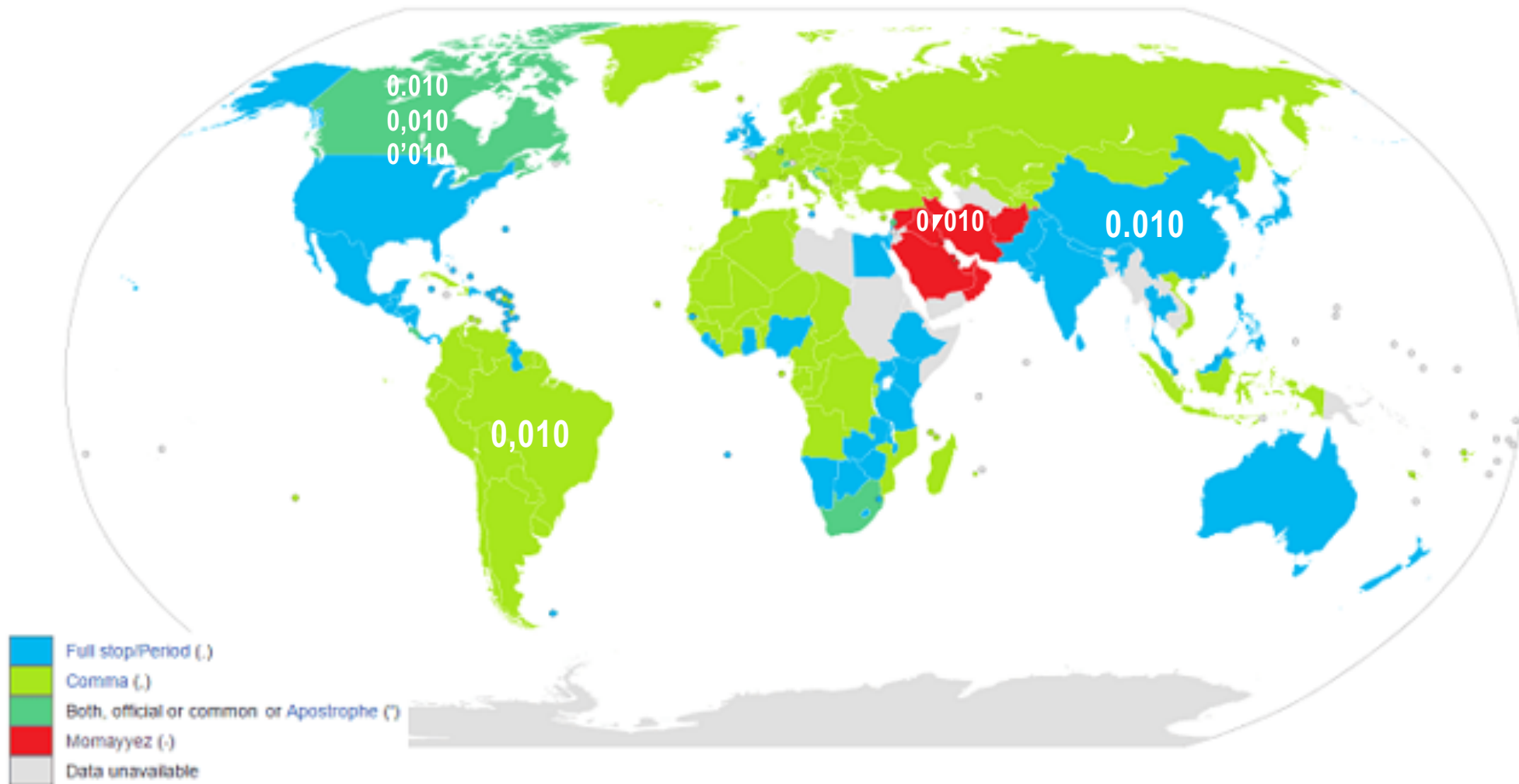
Analyses of Overall Survival (Intention-to-Treat Population)

Study: ABC	Treatment1			Treatment2			Treatment1 vs. Treatment2	
	N	Patients with Event n (%)	Median Time in Months [95 %-CI]	N	Patients with Event n (%)	Median Time in Months [95 %-CI]	Hazard Ratio [95 %-CI]	p-Value
Overall Survival	154	44 (28.6)	4.4 [0.7; 7.7]	151	64 (42.4)	1.14 [0.4; 2.15]	0.60 [0.41; 0.89]	0.010
Overall Survival - Adjusted	154	44 (28.6)	6.4 [4.2; 8.4]	151	46 (30.5)	0.75 [0.08; 1.13]	0.70 [0.46; 1.07]	0.101
Overall Survival - RPSFT	154	44 (28.6)	7.2 [6.5; 8.1]	151	45 (29.8)	0.65 [0.60; 0.71]	0.57 [0.32; 0.86]	0.010
Database Cutoff Date: 31DEC2099								
Number of patients: intention-to-treat								

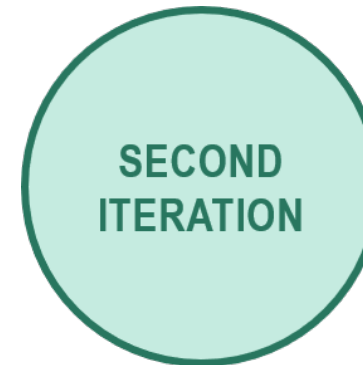
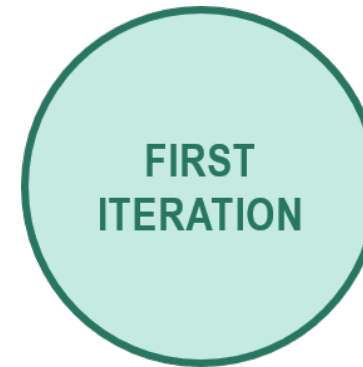
RTF Components

(1) Analyses of Overall Survival (Intention-to-Treat Population)								
(2) Study: ABC	Treatment1			Treatment2			Treatment1 vs. Treatment2	
	N	Patients with Event n (%)	Median Time in Months [95 %-CI]	N	Patients with Event n (%)	Median Time in Months [95 %-CI]	Hazard Ratio [95 %-CI]	p-Value
Overall Survival	154	44 (28.6)	4.4 [0.7; 7.7]	151	64 (42.4)	1.14 [0.4; 2.15]	0.60 [0.41; 0.89]	0.010
Overall Survival - Adjusted (3)	154	44 (28.6)	6.4 [4.2; 8.4]	151 (4)	46 (30.5)	0.75 [0.08; 1.13]	0.70 [0.46; 1.07]	0.101
Overall Survival - RPSFT	154	44 (28.6)	7.2 [6.5; 8.1]	151	45 (29.8)	0.65 [0.60; 0.71]	0.57 [0.32; 0.86]	0.010
Database Cutoff Date: 31DEC2099 Number of patients: intention-to-treat (1)								

Country Specific Formatting Requirements



Decimal separators used around the world (Wikipedia: Decimal separator)



Translated Table (1st iteration)

Analyses of Overall Survival
(Intention-to-Treat Population)

Study: ABC	Treatment1			Treatment2			Treatment1 vs. Treatment2	
	N	Patients with Event n (%)	Median Time in Months [95 %-CI]	N	Patients with Event n (%)	Median Time in Months [95 %-CI]	Hazard Ratio [95 %-CI]	p-Value
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Overall Survival - RPSFT	154	44 (28.6)	7.2 [6.5; 8.1]	151	45 (29.8)	0.65	0.57	0.010
Database Cutoff Date: 31DEC2099								
Number of patients: intention-to-treat								

Analysen von Gesamtüberleben
(Intention-to-Treat Population)

Studie: ABC	Treatment1			Treatment2			Treatment1 vs. Treatment2	
	N	Patienten mit Ereignis n (%)	Mediane Überlebenszeit in Monaten [95 %-KI]	N	Patienten mit Ereignis n (%)	Mediane Überlebenszeit in Monaten [95 %-KI]	Hazard Ratio [95 %-KI]	p-Wert
Gesamtüberleben	154	44 (28,6)	4,4 [0,7; 7,7]	151	64 (42,4)	1,14 [0,4; 2,15]	0,60 [0,41; 0,89]	0,010
Gesamtüberleben - Angepasst	154	44 (28,6)	6,4 [4,2; 8,4]	151	46 (30,5)	0,75 [0,08; 1,13]	0,70 [0,46; 1,07]	0,101
Gesamtüberleben - RPSFT	154	44 (28,6)	7,2 [6,5; 8,1]	151	45 (29,8)	0,65 [0,60; 0,71]	0,57 [0,32; 0,86]	0,010
Datenschnitt: 31. Dec 2099								
Anzahl der Patienten: Intention-to-treat								

Maintenance and updates (1st report)

OUTPUT	SOURCE	ENGLISH_DISPLAY	TRANSLATED_DISPLAY	MATCH
SAMPLE1	HEADER	Treatment	Behandlung	Translated
SAMPLE1	HEADER	Treatment1		Not-Translated
SAMPLE1	HEADER	Treatment2		Not-Translated
SAMPLE1	HEADER	Treatment1 vs. Treatment2		Not-Translated
SAMPLE1	HEADER	Patients with Event	Patienten mit Ereignis	Translated
SAMPLE1	HEADER	Median Time in Weeks	Mediane Überlebenszeit in Monaten	Translated
SAMPLE1	HEADER	N	N	Translated
SAMPLE1	HEADER	n (%)	n (%)	Translated
SAMPLE1	HEADER	[95 %-CI]	[95 %-KI]	Translated
SAMPLE1	HEADER	Hazard Ratio	Hazard Ratio	Translated
SAMPLE1	HEADER	p-Value	p-Wert	Translated

Translated Table (complete)

Analyses of Overall Survival (Intention-to-Treat Population)

Study: ABC	Treatment1			Treatment2			Treatment1 vs. Treatment2	
	N	Patients with Event n (%)	Median Time in Months [95 %-CI]	N	Patients with Event n (%)	Median Time in Months [95 %-CI]	Hazard Ratio [95 %-CI]	p-Value
Overall Survival	154	44 (28.6)	4.4 [0.7; 7.7]	151	64 (42.4)	1.14 [0.4; 2.15]	0.60 [0.41; 0.89]	0.010
Overall Survival - Adjusted	154	44 (28.6)	6.4 [4.2; 8.4]	151	46 (30.5)	0.75 [0.08; 1.13]	0.70 [0.46; 1.07]	0.101
Overall Survival - RPSFT	154	44 (28.6)	7.2 [6.5; 8.1]	151	45 (29.8)	0.65 [0	0.57	0.010

Database Cutoff Date: 31DEC2099

Number of patients: intention-to-treat

Analysen von Gesamtüberleben (Intention-to-Treat Population)

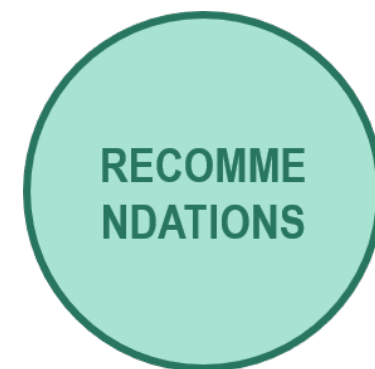
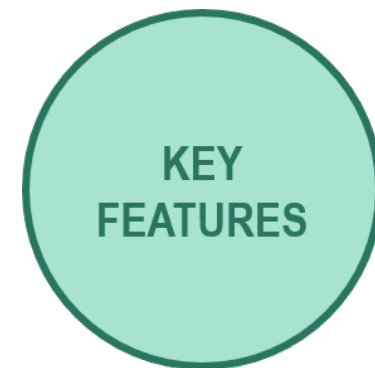
Studie: ABC	Behandlung1			Behandlung2			Behandlung1 vs. Behandlung2	
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Datenschnitt: 31. Dec 2099

Anzahl der Patienten: Intention-to-treat

Maintenance and updates (complete)

OUTPUT	SOURCE	ENGLISH_DISPLAY	TRANSLATED_DISPLAY	MATCH
SAMPLE1	HEADER	Treatment	Behandlung	Translated
SAMPLE1	HEADER	Treatment1	Behandlung1	Translated
SAMPLE1	HEADER	Treatment2	Behandlung2	Translated
SAMPLE1	HEADER	Treatment1 vs. Treatment2	Behandlung1 vs. Behandlung2	Translated
SAMPLE1	HEADER	Patients with Event	Patienten mit Ereignis	Translated
SAMPLE1	HEADER	Median Time in Weeks	Mediane Überlebenszeit in Monaten	Translated
SAMPLE1	HEADER	N	N	Translated
SAMPLE1	HEADER	n (%)	n (%)	Translated
SAMPLE1	HEADER	[95 %-CI]	[95 %-KI]	Translated
SAMPLE1	HEADER	Hazard Ratio	Hazard Ratio	Translated
SAMPLE1	HEADER	p-Value	p-Wert	Translated



Key Features

1. Ease of use
2. Language independent
3. Consistent, reproducible and traceable results
4. Modularity
5. Integration with the existing Analysis & Reporting processes

Recommendations

1. Shared central dictionary across projects for consistent and reproducible results.
2. Automated process for dictionary management.
3. Capability to support more sophisticated table layouts and languages e.g. double byte character languages such as Chinese and Japanese.

Acknowledgements

The authors would like to thank the MSD Biostatistics and Research Decision Sciences (BARDS) HTA group and MSD Sharp & Dohme GmbH HTA Germany colleagues for their contribution and collaboration towards automating and standardizing the translation process.

Your comments and questions are valued and encouraged...

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