

RTF TABLE TRANSLATION AN AUTOMATED APPROACH (PHUSE-SDE ON HTA DOSSIERS)



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Author: Qian Wang

Amit Bhaniani

Business needs for table translation

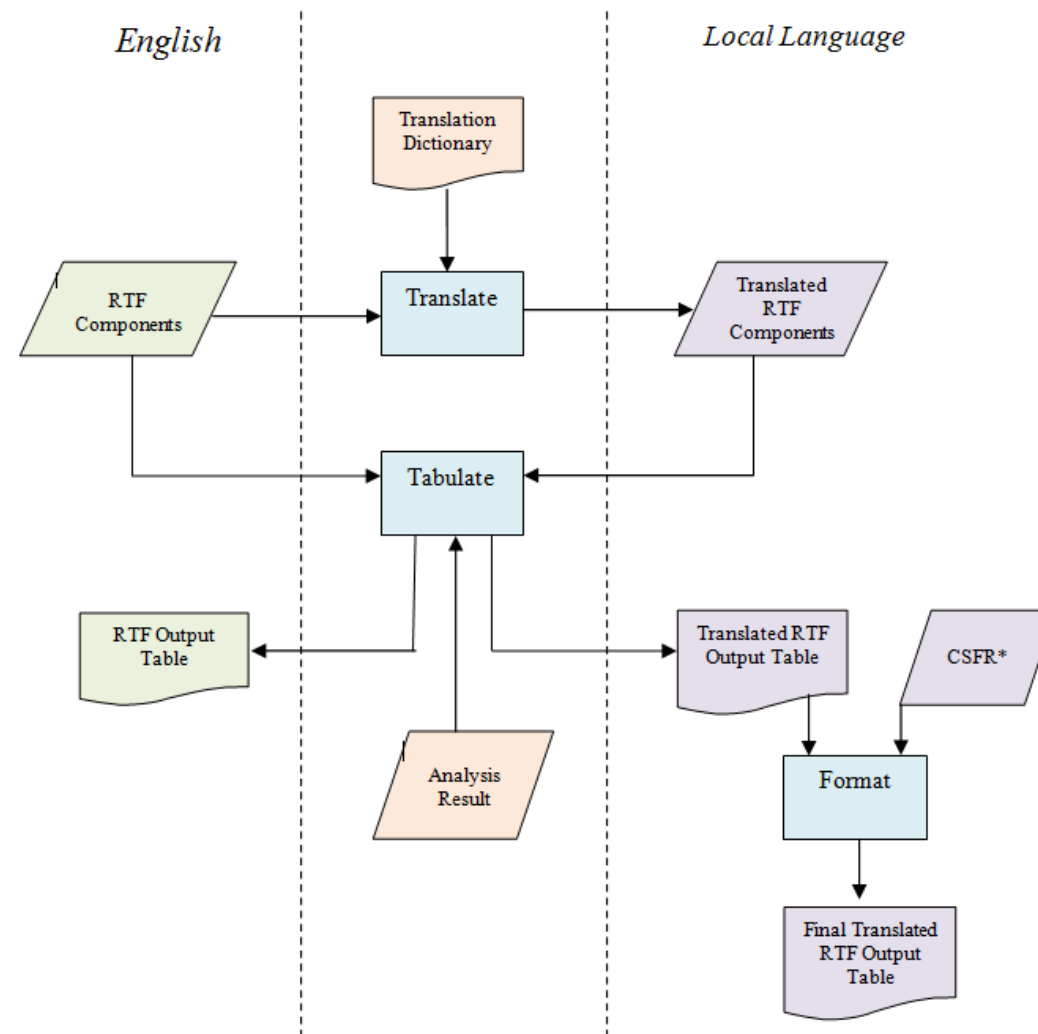
1. Increase in requests for HTA dossiers by countries

- local languages
- size of HTA dossiers

2. Problems with manual translation

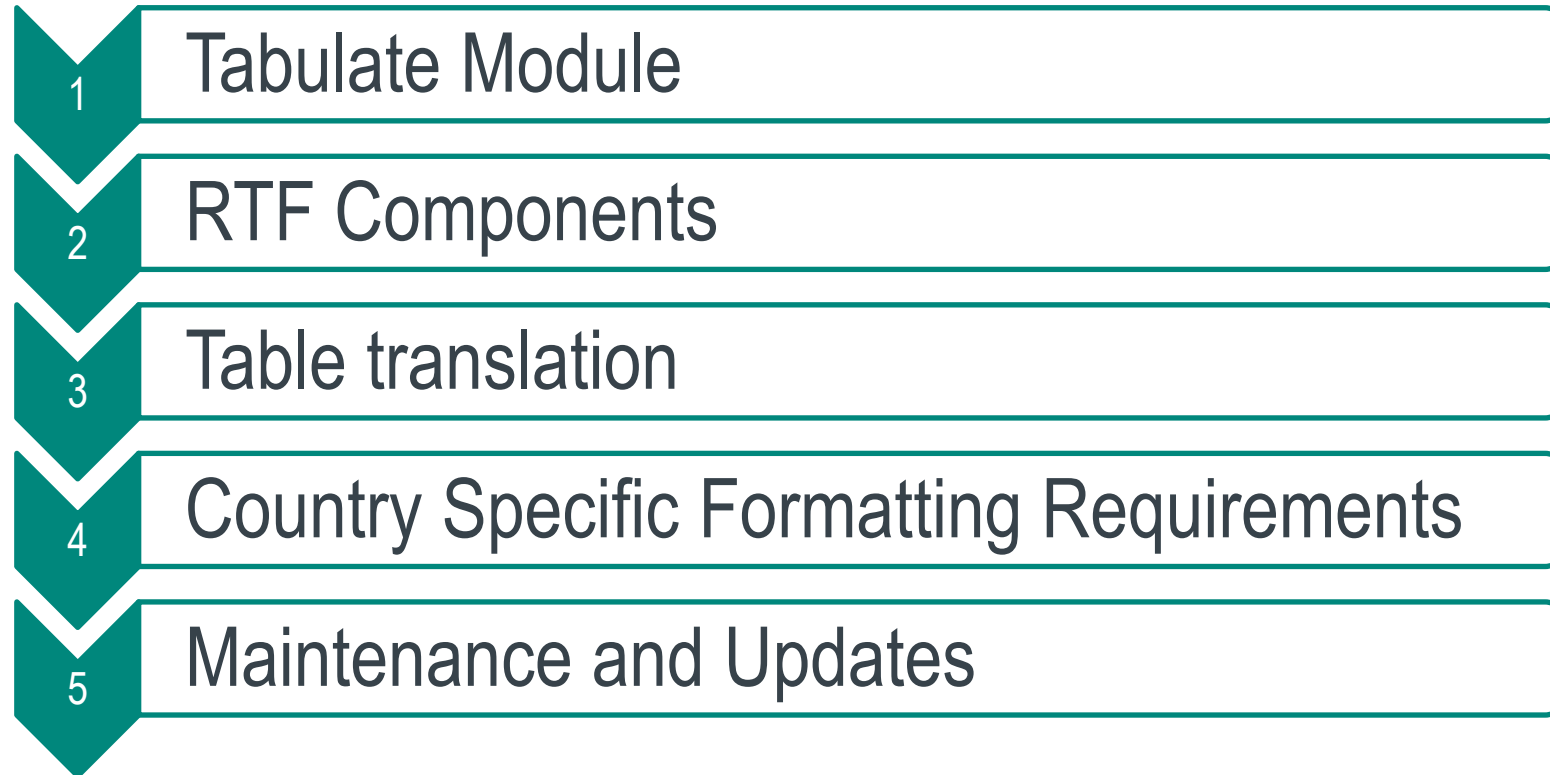
- prone to errors
- time-consuming
- resource intensive
- lacks traceability

RTF table creation and translation flow process



* Country Specific Formatting Requirements

Description of various components of the translation process



Tabulate Module

Time to Adverse Event Related Endpoints

Study: 1234	Treatment			SOC			Treatment vs. SOC	
	N	Patients with Event n (%)	Median Time in Weeks [95 %-CI]	N	Patients with Event n (%)	Median Time in Weeks [95 %-CI]	Hazard Ratio [95 %-CI]	p-Value
Adverse Event 1	100	48 (96.1)	1.1 [0.7; 1.7]	100	45 (96.7)	0.6 [0.4; 0.9]	0.70 [0.60; 0.97]	0.025
Adverse Event 2	100	8 (44.2)	54.1 [27.1; -]	100	6 (44.0)	65.4 [23.1; -]	1.00 [0.71; 1.41]	0.994
Adverse Event 3	100	8 (53.2)	27.1 [18.1; 44.4]	100	10 (72.7)	5.9 [4.4; 9.0]	0.50 [0.36; 0.66]	< 0.001
Adverse Event 4	100	14 (9.1)	Not reached [-; -]	100	21 (14.0)	Not reached [-; -]	0.77 [0.31; 1.19]	0.144
Date: 01MAY2018								

RTF Components

(1) Time to Adverse Event Related Endpoints								
(2) Study: 1234	Treatment			SOC			Treatment vs. SOC	
	N	Patients with Event n (%)	Median Time in Weeks [95 %-CI]	N	Patients with Event n (%)	Median Time in Weeks [95 %-CI]	Hazard Ratio [95 %-CI]	p-Value
Adverse Event 1	100	48 (96.1)	1.1 [0.7; 1.7]	100	45 (96.7)	0.6 [0.4; 0.9]	0.70 [0.60; 0.97]	0.025
Adverse Event 2	100	8 (44.2)	54.1 [27.1; -]	100	6 (4.0)	65.4 [23.1; -]	1.00 [0.71; 1.41]	0.994
Adverse (3)	100	8 (53.2)	27.1 [18.1; 44.4]	100 (4)	10 (12.7)	5.9 [4.4; 9.0]	0.50 [0.36; 0.66]	< 0.001
Adverse Event 4	100	14 (9.1)	Not reached [-; -]	100	21 (14.0)	Not reached [-; -]	0.77 [0.31; 1.19]	0.144
Date: 01MAY2018								
(1)								

Country Specific Formatting Requirements

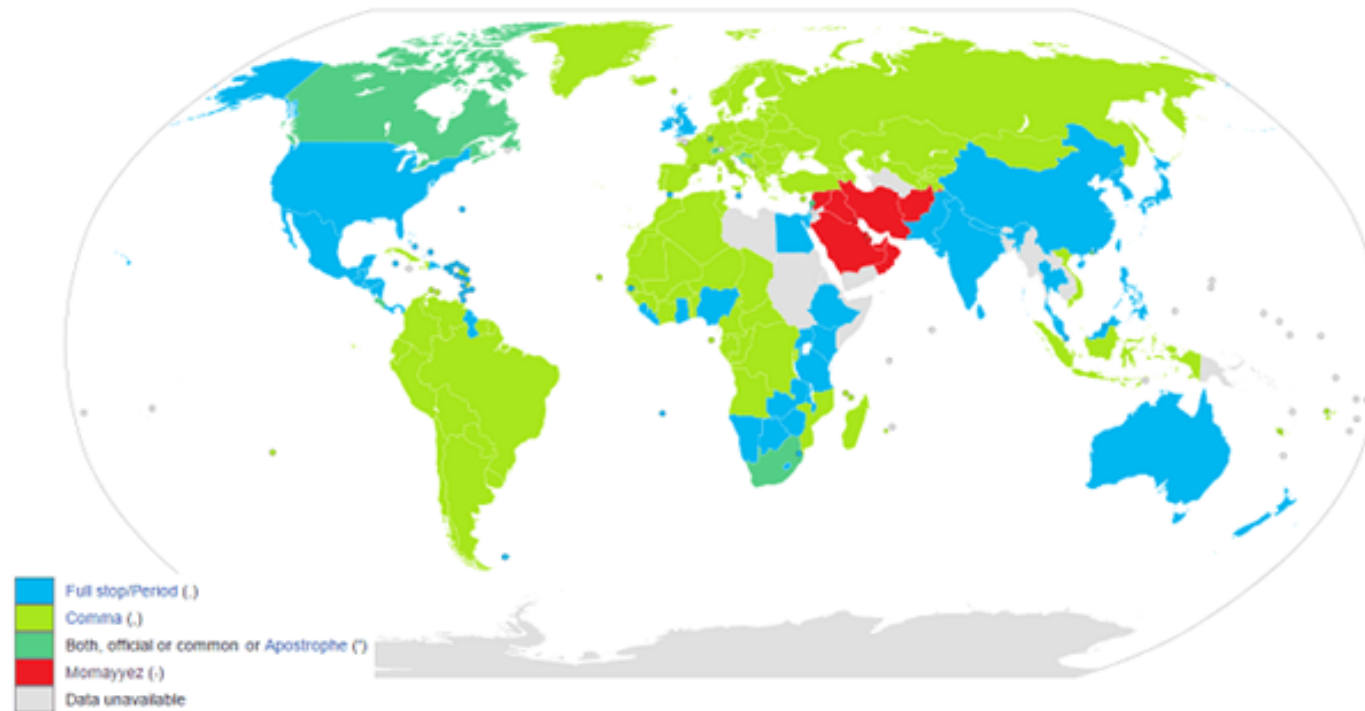


Figure 7 Decimal separators used around the world
(Ref: https://en.wikipedia.org/wiki/Decimal_separator)

Translated Table (1st attempt)

Zeit bis zu unerwünschten ereignisbezogenen Endpunkten

Study: 1234	<u>Behandlung</u>			<u>SOC</u>			Treatment vs. SOC	
	N	<u>Patienten mit Ereignis</u> n (%)	<u>Mediane Überlebenszeit in Wochen</u> [95 %-KI]	N	<u>Patienten mit Ereignis</u> n (%)	<u>Mediane Überlebenszeit in Wochen</u> [95 %-KI]	<u>Hazard Ratio</u> [95 %-KI]	<u>p-Wert</u>
<u>Unerwünschte Ereignisse 1</u>	100	48 (96,1)	1,1 [0,7; 1,7]	100	45 (96,7)	0,6 [0,4; 0,9]	0,70 [0,60; 0,97]	0,025
<u>Unerwünschte Ereignisse 2</u>	100	8 (44,2)	54,1 [27,1; -]	100	6 (44,0)	65,4 [23,1; -]	1,00 [0,71; 1,41]	0,994
<u>Unerwünschte Ereignisse 3</u>	100	8 (53,2)	27,1 [18,1; 44,4]	100	10 (72,7)	5,9 [4,4; 9,0]	0,50 [0,36; 0,66]	< 0,001
Adverse Event 4	100	14 (9,1)	Not reached [-; -]	100	21 (14,0)	Not reached [-; -]	0,77 [0,31; 1,19]	0,144
<u>Datenschnitt: 01 Mai 2018</u>								

Maintenance and updates (1st attempt)

OUTPUT	SOURCE	ENGLISH_DISPLAY	TRANSLATED_DISPLAY	MATCH
SAMPLE1	HEADER	Treatment	Behandlung	Translated
SAMPLE1	HEADER	SOC	SOC	Translated
SAMPLE1	HEADER	Treatment vs. SOC		Not-Translated
SAMPLE1	HEADER	Patients with Event	Patienten mit Ereignis	Translated
SAMPLE1	HEADER	Median Time in Weeks	Mediane Überlebens-zeit in Wochen	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
SAMPLE1	COLUMN	Adverse Event 4		Not-Translated

Translated Table (complete)

Zeit bis zu unerwünschten ereignisbezogenen Endpunkten

Study: 1234	<u>Behandlung</u>			SOC			<u>Behandlung vs. SOC</u>	
	N	<u>Patienten mit Ereignis</u> n (%)	<u>Mediane Überlebenszeit in Wochen</u> [95 %-KI]	N	<u>Patienten mit Ereignis</u> n (%)	<u>Mediane Überlebenszeit in Wochen</u> [95 %-KI]	Hazard Ratio [95 %-KI]	p-Wert
<u>Unerwünschte Ereignisse 1</u>	100	48 (96,1)	1,1 [0,7; 1,7]	100	45 (96,7)	0,6 [0,4; 0,9]	0,70 [0,60; 0,97]	0,025
<u>Unerwünschte Ereignisse 2</u>	100	8 (44,2)	54,1 [27,1; -]	100	6 (44,0)	65,4 [23,1; -]	1,00 [0,71; 1,41]	0,994
<u>Unerwünschte Ereignisse 3</u>	100	8 (53,2)	27,1 [18,1; 44,4]	100	10 (72,7)	5,9 [4,4; 9,0]	0,50 [0,36; 0,66]	< 0,001
<u>Unerwünschte Ereignisse 4</u>	100	14 (9,1)	Not reached [-; -]	100	21 (14,0)	Not reached [-; -]	0,77 [0,31; 1,19]	0,144
Datenschnitt: 01 Mai 2018								

Maintenance and updates (complete)

OUTPUT	SOURCE	ENGLISH_DISPLAY	TRANSLATED_DISPLAY	MATCH
SAMPLE1	HEADER	Treatment	Behandlung	Translated
SAMPLE1	HEADER	SOC	SOC	Translated
SAMPLE1	HEADER	Treatment vs. SOC	Behandlung vs. SOC	Translated
SAMPLE1	HEADER	Patients with Event	Patienten mit Ereignis	Translated
SAMPLE1	HEADER	Median Time in Weeks	Mediane Überlebens-zeit in Wochen	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
SAMPLE1	COLUMN	Adverse Event 4	Unerwünschte Ereignisse 4	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 and Limitations

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

Acknowledgements

The authors would like to thank Carl Herremans, the MSD BARDS HTA group and MSD Germany colleagues for their contribution and collaboration towards automating and standardizing the translation process.

Your comments and questions are valued and encouraged...

Amit Bhaniani
Merck Sharp & Dohme (Europe), Inc.
Pancras Rd 2, Kings Cross,
London N1C 4AG [United Kingdom]
Tel.: +441992452504
E-mail: amit.bhaniani@merck.com
Web: <http://www.msd.com>

Qian Wang
Merck Sharp & Dohme (Europe), Inc.
Clos du Lynx 5,
B-1200 Brussels [Belgium]
Tel: +3227766303
E-mail: qian_wang@merck.com
Web: <http://www.msd.com>





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