

Welcome to CDISC ARS Hackathon!

**HACKATHON**



The diagram illustrates the hackathon process with four stages: 1. IDEA: A yellow lightbulb icon. 2. CONNECT: A blue network icon with a central node and six surrounding nodes. 3. SOLVE: A green icon of two people sitting at a table. 4. PRESENT: A blue icon of a person standing next to a presentation board.

✓ Help operationalize CDISC Analysis Results Model!  
✓ Be an Early Adopter and Gain a Head Start!

cdisc

- Einführung in ARS (Analysis Result Standard)
- Diskussion von möglichen Erweiterungen des Modells
- Ideen diskutiert wie ARS in den einzelnen Prozessen genutzt werden kann
- Man hatte die Gelegenheit selber mit dem Model zu arbeiten und Lösungen für Prozessteile zu entwickeln
- Die Teilnehmer konnten ihre Lösungen vorstellen

# Aktuelle Situation

Study - CDISC 360

Page x of y

Table 14.1.1  
Summary of Demographics  
Safety Population

Characteristics	Placebo (N=%)	Vanomeline Low Dose (N=%)	Vanomeline High Dose (N=%)
Age (years)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Age Group, n (%)			
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender, n (%)			
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

Source dataset: adsl, Generated on: DDMONYYYY:HH:MM  
Program: <pid>.sas, Output: <pid><oid>.rft, Generated on: DDMONYYYY:HH:MM

Results

## Nachbauen der Mocktables

- Style template
- RTF statements zu den Results hinzufügen, um Leerzeilen, Zeilenumbrüche und Einrücken zu erzwingen
- Proc report:
  - Spalten- und Zeilen- Eigenschaften / Überschriften definieren
  - Tabelleneigenschaften definieren
  - Seiten- und Zeilenumbrüche definieren
- Title, Fussnoten einfügen (manuell oder aus externen Dateien)
- Alle TLFs in einer Datei zusammenführen und mit TOC versehen

# Mein Traum

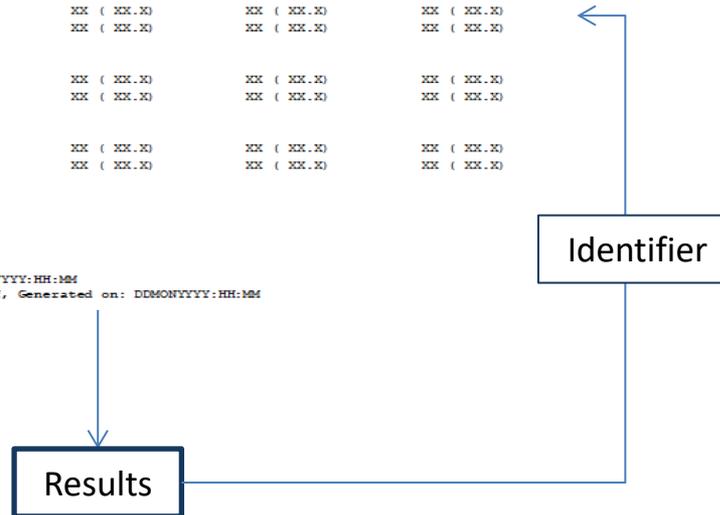
Study - CDISC 360

Page x of y

Table 14.1.1  
Summary of Demographics  
Safety Population

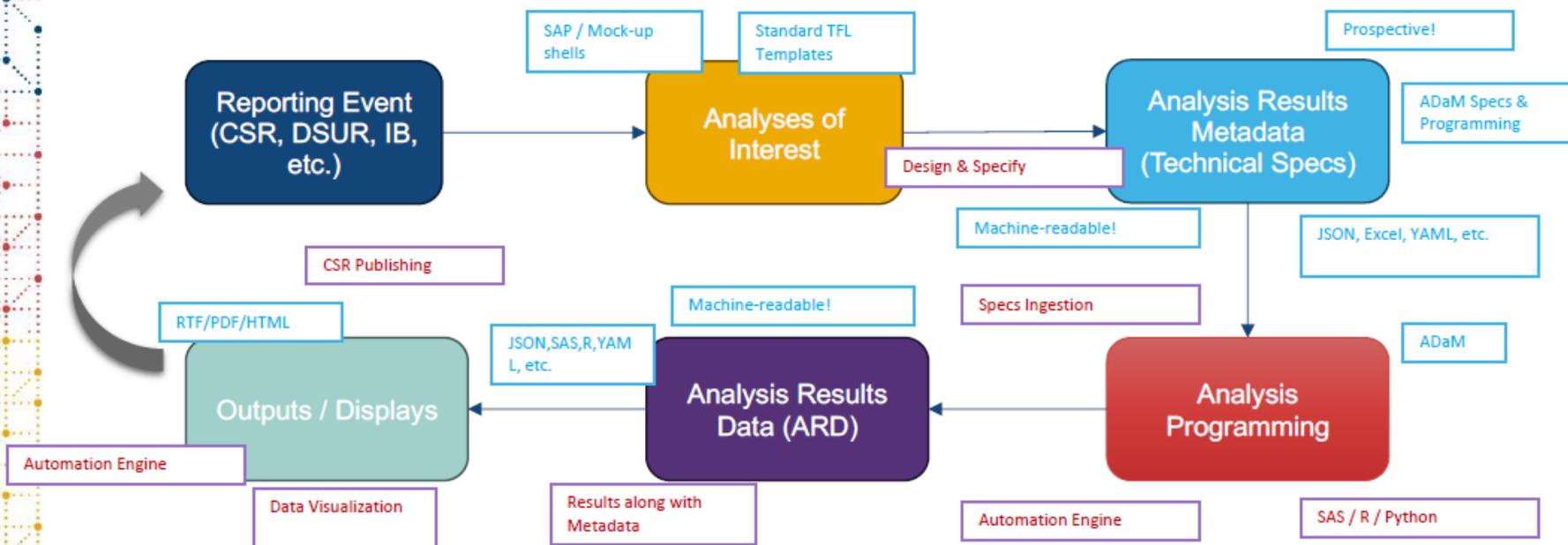
Characteristics	Placebo (N=%)	Vanomeline Low Dose (N=%)	Vanomeline High Dose (N=%)
Age (years)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Age Group, n (%)			
< 65 years	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
≥ 65 years	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Gender, n (%)			
Male	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Female	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Not Hispanic or Latino	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)

Source dataset: adsl, Generated on: DEMONYYYY:HH:MM  
Program: <pid>.sas, Output: <pid><oid>.ref, Generated on: DEMONYYYY:HH:MM



→ ARS machts möglich? Das wollte ich wissen....

# ARS Model Supported Workflow and Entry Points





# Wie die Informationen von Mocktables in ARS systematisch in Klassen abgespeichert werden

## Review Examples



### Summary of Demographics

Study - CDISC 360 Page x of y

Table 14.1.1.1  
Summary of Demographics  
Safety Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age (years)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Age Group, n (%)			
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gender, n (%)			
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)

Source dataset: adsl, Generated on: DEMONYTY:SH:MM  
Program: <pid>.sas, Output: <pid><cid>.rtf, Generated on: DEMONYTY:SH:MM

### Summary of TEAE by SOC and PT

Study - CDISC 360 Page x of y

Table 14.3.1.1  
Summary of TEAE by System Organ Class and Preferred Term  
Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)
...	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Preferred Term m>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<SOC 2>	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)
...	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)

Notes: TEAE=Treatment-Emergent Adverse Events.  
Subjects are counted once within each system organ class and preferred term.  
[a] All investigators adverse events were coded using MedDRA version xx.x.

Source dataset: adae, Generated on: DEMONYTY:SH:MM  
Program: <pid>.sas, Output: <pid><cid>.rtf, Generated on: DEMONYTY:SH:MM

Überschriften, Fussnoten, sonstige Beschriftungen werden in der Klasse OutputDisplay, bestehend aus verschiedenen DisplaySections, abgespeichert.

## Review Examples

### Summary of Demographics

Study - CDISC 360 Page x of y

Table 14.2.1  
Summary of Demographics  
Safety Population

Characteristic	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Age (years)			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Age Group, n (%)			
< 65 years	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
≥ 65 years	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Gender, n (%)			
Male	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Female	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Ethnicity, n (%)			
Hispanic or Latino	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
Not Hispanic or Latino	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)

Source dataset: sda1, Generated on: DDMMYYYY:HH:MM  
 Program: <pid>.sas, Output: <pid><cid>.rtf, Generated on: DDMMYYYY:HH:MM

### Summary of TEAE by SOC and PT

Study - CDISC 360 Page x of y

Table 14.3.1.1  
Summary of TEAE by System Organ Class and Preferred Term  
Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<SOC 1>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<Preferred Term 1>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
...	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<Preferred Term n>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<SOC 2>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<Preferred Term 1>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
...	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)
<Preferred Term n>	XX ( XX.X)	XX ( XX.X)	XX ( XX.X)

Notes: TEAE=Treatment-Emergent Adverse Events.  
 Subjects are counted once within each system organ class and preferred term.  
 [a] All investigators adverse events were coded using MedDRA version XX.X.

Source dataset: sda2, Generated on: DDMMYYYY:HH:MM  
 Program: <pid>.sas, Output: <pid><cid>.rtf, Generated on: DDMMYYYY:HH:MM

Results und Metadaten sind in separaten Klassen gespeichert → ermöglicht Trennung der Table Spezifikation und Erzeugung der Results

## Analysis Results and Associated Metadata Example

Identifiers		Analysis Group			Result Variable			Results Statistic		
Name	Title	Dataset	Variable	Value	Variable	Value	Label	Value	Name	Label
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	53	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	61.6	Percent	%
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	33	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	38.4	Percent	%

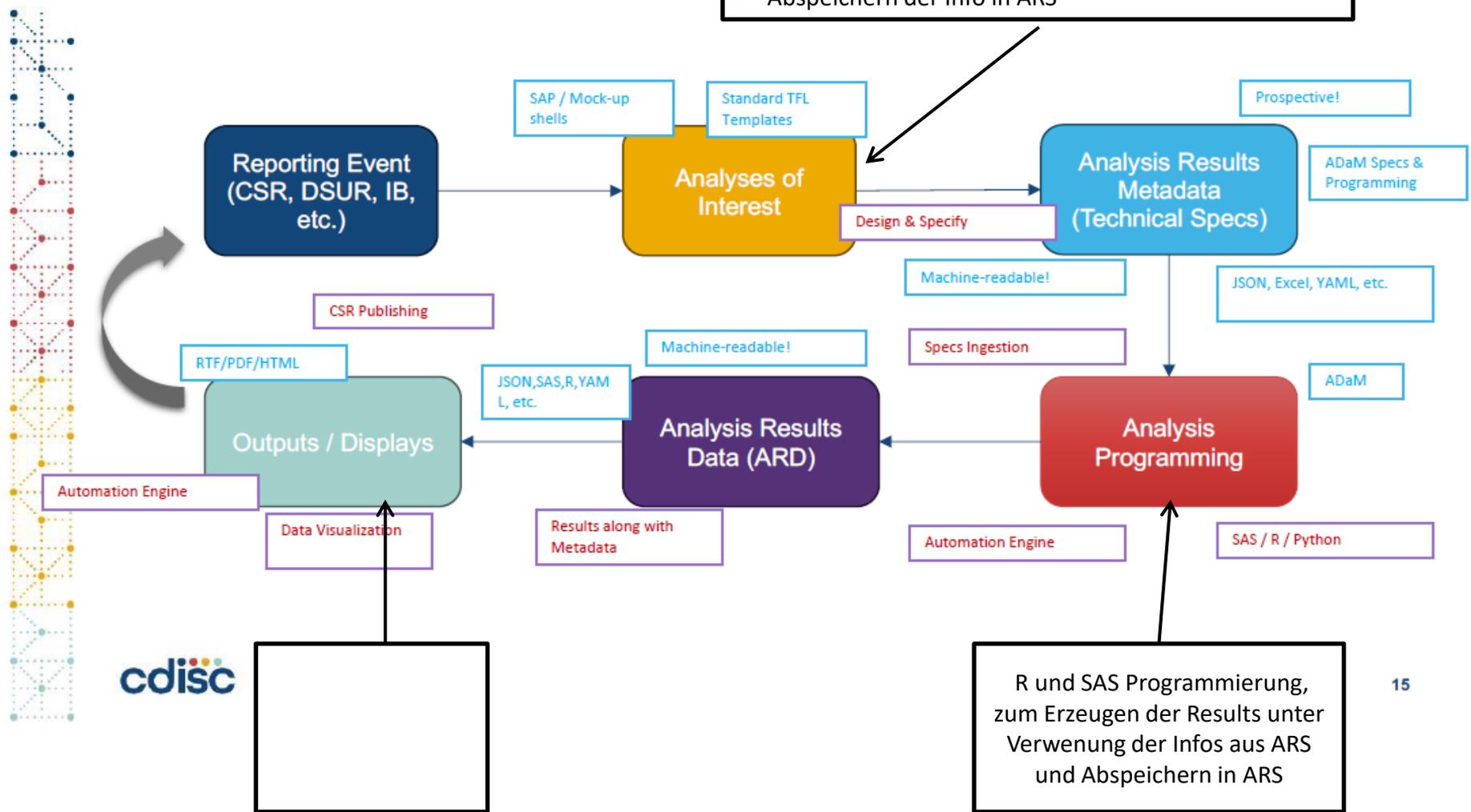
Was es schon gibt:

TLF Designer:

<https://clymbclinical.com/tfl-designer/>

Anwendung um Technical Specs zu erstellen.

- Dialoge mit denen man die Infos der Mocktables festlegen kann.
- Drop down Menüs wahlweise mit ADaM datasets hinterlegt.
- Startpunkt, auswählbares Template
- Abspeichern der Info in ARS



### Who attended the workshop:

- Clinical / Statistical Programmer (**63%**)
- Biostatisticians (**14%**)
- Data Standards Expert (**13%**)
- Other (**12%**)

### Top 5 pain points:

1. Too much variability across studies / disease areas / organizations
2. No industry-wide standards exist
3. TFL metadata and shells are not machine-readable
4. Multiple manual steps in the process
5. Limited or no automation exist

Programming is more of a Science (**50%**) than it is an Art (**39%**)!



Bhavin Busa



**74%** organization have TFL standards or templates

Who generates TFL shells (mock-ups)?  
**57%** - Biostatistician  
**31%** - Biostats & Programmers

**87%** responders confirmed their TFL shells are NOT machine-readable

**65%** responders uses MS Word / RTF for TFL shells generation

**40%** annotate their TFL mock-up shells to provide results metadata information

**76%** do not generate analysis results metadata prospectively to use in their TFL program

**82%** confirmed not having machine-readable TFL analysis results metadata

Out of the responders who use machine-readable ARM: MS Excel (**14%**) and SAS (**10%**) are top 2 format choices



## Fazit:

- ARS ermöglicht die Entwicklung von Anwendungen, die Machine readable Mocktables erzeugen. (→Software Entwickler)
- In ARS abgelegte Informationen können in SAS bzw. R eingelesen werden und verwendet werden, um die Ergebnisse zu erzeugen.
- Es wurde keine Lösung vorgestellt bzw. innerhalb des Projekts entwickelt, zur Ausgabe der Ergebnisse
- Was ich suche gibt es noch nicht.
- ARS ermöglicht vielleicht die Entwicklung einer solchen Anwendung
- In ARS ist noch kein Konzept vorgesehen zur Integration von Grafiken
- Das ARS Team sucht Zusammenarbeit und Feedback

Wer es genauer wissen will:

<https://www.cdisc.org/events/webinar/introduction-analysis-results-standards>

<https://www.pharmasug.org/proceedings/2023/MM/PharmaSUG-2023-MM-327.pdf>

Paper DS09 CDISC Analysis Results Standard – Update and Progress

<https://cdisc-org.github.io/analysis-results-standard/> (Dokumentation des Datenmodels)

<https://github.com/cdisc-org/analysis-results-standard> (Dokumentation, Beispiele, Programme etc.)

Standard Safety Tables and Figures – Integrated Guide

[https://downloads.regulations.gov/FDA-2022-N-1961-0046/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2022-N-1961-0046/attachment_1.pdf)

