

Patient Narrative is a document that describes the clinical experience of a subject in a clinical trial. It is required to be included as part of Clinical Study Report (CSR) for the regulatory agency as per International Conference on Harmonization (ICH) E3 guidelines. Patient Narrative is triggered by significant events that happened to a subject in a trial such as serious adverse event, death or event of special interest. The process of creating Patient Narrative can be automated to generate **patient-level listings** as well as **graphs** to provide useful insights. The paper integrates listings and graphs in an easy to use HTML dashboard-style layout.

Patient Profile Graphs

Plots for Patient ID = ABC-1001

Report Item	Description	(Click to view)
1	Adverse Events	AE
2	Concomitant Medications	CM
3	Laboratory Results	LB
4	Efficacy	EFF



Patient Narrative Table of Contents

Subject ID	Criteria			
	Serious AE	Immune-related AE	AE of Special Interest	Death
ABC-1001	x			
ABC-1002	x	x		
ABC-1003			x	
ABC-1004		x	x	
ABC-1005	x			x
ABC-1006	x			
ABC-1007	x		x	
ABC-1008	x			x
ABC-1009		x		
ABC-1010			x	

The below [dashboard](#) in HTML format gives a summary of patients meeting the necessary event criteria to be considered for Patient Narrative. Key hyperlinks generated are explained below:

- **Link #1** creates individual patient-level safety and efficacy graphs
- **Link #2** creates a Table of Content to be included in Patient Narrative document
- **Link #3** creates a detailed patient listing in RTF format which can included in CSR

Subject ID	Criteria				Create TOC
	Serious AE	Immune-related AE	AE of Special Interest	Death	
ABC-1001	x				Subj_ABC-1001.rtf
ABC-1002	x	x			Subj_ABC-1002.rtf
ABC-1003			x		Subj_ABC-1003.rtf
ABC-1004		x	x		Subj_ABC-1004.rtf
ABC-1005	x			x	Subj_ABC-1005.rtf
ABC-1006	x				Subj_ABC-1006.rtf
ABC-1007	x		x		Subj_ABC-1007.rtf
ABC-1008	x			x	Subj_ABC-1008.rtf
ABC-1009		x			Subj_ABC-1009.rtf
ABC-1010			x		Subj_ABC-1010.rtf

Patient Narrative RTF Listing

Subject Details							
Subject ID: ABC-1001							
Event: Subject had Serious AE= Fever. Start Dt= 01-Mar-2019 , End Dt= 15-Mar-2019, Action taken=None							
Demographics: 65 yrs old, Male, White, USA							
Treatment Arm: Active (Start Dt= 25-Feb-2019, End Dt= Ongoing)							

Subject ID	Preferred Term	Onset Date	Stop Date	Ongoing	Severity	Action taken	Causality
ABC-1001	FEVER	01MAR2019	15MAR2019		Severe	None	Not-Related
	VOMITTING	10APR2019	11APR2019		Mild	None	Not-Related
	DIARRHEA	19APR2019	25APR2019		Moderate	None	Related
	HEADACHE	01MAY2019	05MAY2019		Moderate	None	Not-Related
	COUGH	08APR2019		Ongoing	Mild	None	Not-Related
	DIZZINESS	03APR2019	06APR2019		Mild	None	Not-Related

Subject ID	Concomitant Med	Indication	Start Date	Stop Date	Ongoing	Route	Frequency
ABC-1001	Ibuprofen	IBS	01MAR2019	15MAR2019		Oral	Daily
	Corticosteroids	IBS	15APR2019	25MAY2019		Injection	Once
	Cyclizine	IBS	25MAR2019	31MAR2019		Oral	Daily
	Kaopectate	IBS	01APR2019	20APR2019		Oral	Daily
	Aspirin	IBS	08APR2019		Ongoing	Oral	Daily

PROGRAMMING NOTE:

Dynamic hyperlinks can be created from a dataset as:

```
data out;
set in;
sublink= strip(usubjid)||'_Plots.html';
* - USUBJID holds Subject ID like ABC-1001;
link = '<a'
      ||compress('href='||sublink||'>')
      ||strip(usubjid) ||'</a>';
run;

ods html style=default path="&path\"
         (url=none) body='TOC.html';

proc report data=out;
<..... lines of code ..... >
define link / display 'Subject ID';
```

CONCLUSION:

The paper presented a graphical approach to Patient Narrative to provide additional insight which can aid in more robust narrative. Users are encouraged to use the templates provided here to develop custom templates meeting their individual study needs

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