

Patient Profile with Color-Coded Track Changes Since Last Review

Himanshu Patel, Jeff Xia, Merck & Co., Inc., Rahway, NJ, USA

ABSTRACT

Patient profile is a summary of events experienced by patients during the conduct of a clinical trial. It gives a clear understanding of patient encounters and offers a more focused on methodology by recognizing abnormalities in the data. To ensure patient safety and monitor the significant clinical event, study clinical scientists have the responsibility to review subject patient profiles periodically during the conduct of the trial. However, the existing patient profiles generated in the data management system displays subject data in an accumulative way, which means clinical scientists have to review many data records again even they have reviewed them multiple times in previous rounds. It becomes a more and more time-consuming and attention-demanding task for clinical scientists to find the information of interest, such as the new emerging data, data altered/updated since last round of review or records that have been removed in the data cleaning process.

This paper presents an innovative way to compare the current data extraction against the last one programmatically, and generates patient profiles with color-coded changes: For records with no change since last round of review, the entire row will be set to the color of Cyan to let clinical scientists know there is no need to review them again. On the other hand, new records will be set to Yellow to draw reviewers attention, and the removed records will be set to Green. If some data points in a row got updated since the last review, the new value(s) would be highlighted in Red to differentiate with other data points with no change, and the old value(s) for the change will be displayed in the row underneath. It provides an efficient way for clinical scientists to understand what the new values are, and what are the old ones so that they can evaluate what the impacts are.

INTRODUCTION

One of the most useful tools to review the data for a clinical team is a patient profile. However, as the clinical trial progress, it accumulates the data and spans many pages which can be challenging to review and take much longer time. At this point, the listing typically contains all available data while not highlight precisely what has been added or updated since the last review. The clinical team needs to go through the review process and manually identify the new data which in the clinical interest. There should be an efficient way to track the changes, addition, and modification to the data in the patient profile since the last review.

The paper will demonstrate an efficient way to track changes in data since the last review with color-coded information. The information retrieved from this paper plays a crucial role for the clinical team especially when they are planning to review patient profile multiple time over the period for the same study.

The only qualifications for this macro to work are as follows:

1. At least the most recent version of the old dataset must be available in the same or different location for comparison purposes.

EXAMPLE

We are going to use a simple version of the sample data collected during the clinical trial which required to generate a patient profile. The following data is an Adverse Event data that is collected in all studies and always in the scope of clinical importance. ***Please note that the following sample data is for illustrative purpose only.***

Unique Subject Identifier	Reported Term for the Adverse Event	Dictionary-Derived Term	Body System or Organ Class	Start Date of Adverse Event	End Date of Adverse Event
MK999-PN999	Visual discomfort, bilateral	Ocular discomfort	Eye disorders	1996-12-26	1997-02-13
MK999-PN999	conjunctivitis	Conjunctivitis	Infections and infestations	1997-01-03	1997-02-13
MK999-PN999	Dry eye	Dry eye	Eye disorders	1997-01-03	1997-02-13
MK999-PN999	eczema	Eczema	Skin and subcutaneous tissue disorders	1997-02-02	1997-02-23
MK999-PN999	Senile cataract (OD)	Cataract	Eye disorders	1997-01-06	1997-02-13
MK999-PN999	bilateral foot edema	Oedema peripheral	General disorders and administration site conditions	1997-03-05	
MK999-PN999	Dry mouth	Dry mouth	Gastrointestinal disorders	1997-04-27	1998-06-07
MK999-PN999	Elevated asparate aminotransferase	Asparate aminotransferase increased	Investigations	1997-11-09	1997-12-22
MK999-PN999	Elevated alanine aminotransferase	Alanine aminotransferase increased	Investigations	1997-11-09	1997-12-22

Figure 1. Let's assume this was the data collected as of the last clinical review.

FEATURE 1: IDENTIFY RECORDS WITHOUT CHANGES SINCE LAST REVIEW

This is a common situation as the new data accumulates with the old data periodically. With the programming approach, it is possible to highlight the old records which were reviewed by the clinical team in the last review. Row without changes in the data display with **Cyan** color background and status as **No Change**.

Status	Unique Subject Identifier	Reported Term for the Adverse Event	Dictionary-Derived Term	Body System or Organ Class	Start Date of Adverse Event	End Date of Adverse Event
NO CHANGE	MK999-PN999	Visual discomfort, bilateral	Ocular discomfort	Eye disorders	1996-12-26	1997-02-13
NO CHANGE	MK999-PN999	conjunctivitis	Conjunctivitis	Infections and infestations	1997-01-03	1997-02-13
NO CHANGE	MK999-PN999	Dry eye	Dry eye	Eye disorders	1997-01-03	1997-02-13
NO CHANGE	MK999-PN999	eczema	Eczema	Skin and subcutaneous tissue disorders	1997-02-02	1997-02-23
NO CHANGE	MK999-PN999	Senile cataract (OD)	Cataract	Eye disorders	1997-01-06	1997-02-13
NO CHANGE	MK999-PN999	bilateral foot edema	Oedema peripheral	General disorders and administration site conditions	1997-03-05	
NO CHANGE	MK999-PN999	Dry mouth	Dry mouth	Gastrointestinal disorders	1997-04-27	1998-06-07
NO CHANGE	MK999-PN999	Elevated asparate aminotransferase	Asparate aminotransferase increased	Investigations	1997-11-09	1997-12-22
NO CHANGE	MK999-PN999	Elevated alanine aminotransferase	Alanine aminotransferase increased	Investigations	1997-11-09	1997-12-22

Figure 2. Identify records without changes compared to data in [Figure 1](#). (For Illustrative Purpose Only)

FEATURE 2: IDENTIFY NEW RECORDS SINCE LAST REVIEW

Now that you have updated data, it is vital to identify the new records compare to old data and highlight it. It gives flexibility to the reviewer and also saves time in the overall review process. With the programming enhancement, newly added records display with **Yellow** color background and status as **Added** while the old records with **Cyan** color background and status as **No change**.

Status	Unique Subject Identifier	Reported Term for the Adverse Event	Dictionary-Derived Term	Body System or Organ Class	Start Date of Adverse Event	End Date of Adverse Event
NO CHANGE	MK999-PN999	Visual discomfort, bilateral	Ocular discomfort	Eye disorders	1996-12-26	1997-02-13
NO CHANGE	MK999-PN999	conjunctivitis	Conjunctivitis	Infections and infestations	1997-01-03	1997-02-13
NO CHANGE	MK999-PN999	Dry eye	Dry eye	Eye disorders	1997-01-03	1997-02-13
NO CHANGE	MK999-PN999	eczema	Eczema	Skin and subcutaneous tissue disorders	1997-02-02	1997-02-23
NO CHANGE	MK999-PN999	Senile cataract (OD)	Cataract	Eye disorders	1997-01-06	1997-02-13
NO CHANGE	MK999-PN999	bilateral foot edema	Oedema peripheral	General disorders and administration site conditions	1997-03-05	
NO CHANGE	MK999-PN999	Dry mouth	Dry mouth	Gastrointestinal disorders	1997-04-27	1998-06-07
NO CHANGE	MK999-PN999	Elevated asparate aminotransferase	Asparate aminotransferase increased	Investigations	1997-11-09	1997-12-22
NO CHANGE	MK999-PN999	Elevated alanine aminotransferase	Alanine aminotransferase increased	Investigations	1997-11-09	1997-12-22
ADDED	MK999-PN999	Halitosis	Breath odour	Gastrointestinal disorders	1997-12-10	
ADDED	MK999-PN999	Pyrosis	Dyspepsia	Gastrointestinal disorders	1997-12-25	

Figure 3. Identify new records compared to data in [Figure 1](#). (For Illustrative Purpose Only)

FEATURE 3: IDENTIFY DELETED RECORDS SINCE LAST REVIEW

Removal of the records from the database is not standard practice, and it occurs in the rare case with some explainable situation. Therefore, identifying the deleted records in the new database compared to the old dataset is the most critical items to review for the clinical team. With the enhanced programming techniques, programming team can identify such scenario and report it. In the following screenshot, deleted records from the old database display with **Green** color background and status as **Removed** while the unchanged records display with **Cyan** color background and status as **No Change**.

Status	Unique Subject Identifier	Reported Term for the Adverse Event	Dictionary-Derived Term	Body System or Organ Class	Start Date of Adverse Event	End Date of Adverse Event
NO CHANGE	MK999-PN999	Visual discomfort, bilateral	Ocular discomfort	Eye disorders	1996-12-26	1997-02-13
NO CHANGE	MK999-PN999	conjunctivitis	Conjunctivitis	Infections and infestations	1997-01-03	1997-02-13
NO CHANGE	MK999-PN999	Dry eye	Dry eye	Eye disorders	1997-01-03	1997-02-13
REMOVED	MK999-PN999	URI	Upper respiratory tract infection	Infections and infestations	1997-01-22	1997-02-07
NO CHANGE	MK999-PN999	eczema	Eczema	Skin and subcutaneous tissue disorders	1997-02-02	1997-02-23
NO CHANGE	MK999-PN999	Senile cataract (OD)	Cataract	Eye disorders	1997-01-06	1997-02-13
NO CHANGE	MK999-PN999	bilateral foot edema	Oedema peripheral	General disorders and administration site conditions	1997-03-05	
NO CHANGE	MK999-PN999	Dry mouth	Dry mouth	Gastrointestinal disorders	1997-04-27	1998-06-07
NO CHANGE	MK999-PN999	Elevated asparate aminotransferase	Asparate aminotransferase increased	Investigations	1997-11-09	1997-12-22
NO CHANGE	MK999-PN999	Elevated alanine aminotransferase	Alanine aminotransferase increased	Investigations	1997-11-09	1997-12-22
REMOVED	MK999-PN999	UTI	Urinary tract infection	Infections and infestations	1997-11-27	1997-11-27

Figure 4. Identify deleted records compared to data in [Figure 1](#). (For Illustrative Purpose Only)

FEATURE 4: IDENTIFY CHANGES IN DATA POINT SINCE LAST REVIEW

In the above sections, we covered the situation such as identifying the records without changes, new records and deleted records as compared to the old database. However, it is also common to have the same records with some changed or updated data points. For the reviewer, it is very challenging to identify such changes, and therefore it is crucial to detect such changes and report it. In the following example, records are the same as compared to the old database, but it's corresponding AE terms, and AE start date changed. In such a situation, the program will identify records with changes in the data point and provide the following details:

- Highlight old records in **Grey** color background and status as **Old**.
- Display new records with the following:
 - Without any background color
 - Highlight changed data point in **Red** color background and status as **Updated**.
- Highlight unchanged records in **Cyan** color background and status as **No Change**.

Status	Unique Subject Identifier	Reported Term for the Adverse Event	Dictionary-Derived Term	Body System or Organ Class	Start Date of Adverse Event	End Date of Adverse Event
NO CHANGE	MK999-PN999	Visual discomfort, bilateral	Ocular discomfort	Eye disorders	1996-12-26	1997-02-13
NO CHANGE	MK999-PN999	conjunctivitis	Conjunctivitis	Infections and infestations	1997-01-03	1997-02-13
NO CHANGE	MK999-PN999	Dry eye	Dry eye	Eye disorders	1997-01-03	1997-02-13
NO CHANGE	MK999-PN999	eczema	Eczema	Skin and subcutaneous tissue disorders	1997-02-02	1997-02-23
NO CHANGE	MK999-PN999	Senile cataract (OD)	Cataract	Eye disorders	1997-01-06	1997-02-13
NO CHANGE	MK999-PN999	bilateral foot edema	Oedema peripheral	General disorders and administration site conditions	1997-03-05	
NO CHANGE	MK999-PN999	Dry mouth	Dry mouth	Gastrointestinal disorders	1997-04-27	1998-06-07
UPDATED	MK999-PN999	Elevated asparate aminotransferase worsening	Asparate aminotransferase increased	Investigations	1997-11-10	1997-12-22
OLD	MK999-PN999	Elevated asparate aminotransferase	Asparate aminotransferase increased	Investigations	1997-11-09	1997-12-22
UPDATED	MK999-PN999	Elevated alanine aminotransferase worsening	Alanine aminotransferase increased	Investigations	1997-11-10	1997-12-22
OLD	MK999-PN999	Elevated alanine aminotransferase	Alanine aminotransferase increased	Investigations	1997-11-09	1997-12-22

Figure 5. Identify changes in data point compared to data in [Figure 1](#). (For Illustrative Purpose Only)

FEATURE 5: SUMMARY LISTING WITH ALL CHANGES SINCE LAST REVIEW

The patient profile contains multiple types of data such as Medical History, Concomitant Medication, Adverse Events, Dose Summary, Procedures, Efficacy End Points, Laboratory Data and many more based on the study requirements or therapeutic areas. Even though we provide a patient profile with color-coded track changes, the reviewer has to open individual RTF file to determine whether there are changes or updates, which might be very time-consuming if there are hundreds of subjects to review. Is there any way to overcome the challenge? The answer is **Yes**.

With the help of SAS® Programming, we can scan each file and identify the changes in each section compared to the old database. The program output the findings in a PDF format. In the following screenshot, comments columns provide the differences in each section of a patient profile for each subject.

For Example:

For subject '333333', the program identified the changes in section # 3 and section # 14 and provided the details in the comment section. That means for this subject, there is no change in the other sections, and all data are the same since the last review.

Empty comment rows identify that there is no change in any section of the profile since the last review. The reviewer can choose to skip reviewing these files based on their judgment.

With this approach, the reviewer can look at the PDF listing first and identify how many subjects have changed in data since the last review. They can pick up only those profiles and directly go to the section where changes highlighted. By doing this, they will save a lot of time and efforts of scanning all pages of each subject.

Study PNxxx
Addition or Update or Removal in Patient Profile
(Run at yyyy-mm-ddT hh:mm:ss)

Obs	Subject Randomization Number	Unique Subject Identifier	Comments
1	111111	MK111-PN111	Addition or Update or Removal in L4
2	222222	MK222-PN222	Addition or Update or Removal in L2
3	333333	MK333-PN333	Addition or Update or Removal in L3 L14
4	444444	MK444-PN444	
5	555555	MK555-PN555	
6	666666	MK666-PN666	Addition or Update or Removal in L14
7	777777	MK777-PN777	
8	888888	MK888-PN888	Addition or Update or Removal in L3 L4 L12 L14
9	999999	MK999-PN999	Addition or Update or Removal in L3 L6 L10 L12 L14

Figure 6. Identify changes in each section of the file and provide a summary in a PDF format.

CONCLUSION

Many people in the clinical industry review patient profile frequently. Dealing with such massive data and the number of files is a complex and challenging task and also required many efforts. One minor mistake or overseen of data can cause some serious implications. With the help of color-coded track change programming techniques, we overcome the challenges and give the reviewer a reliable review platform. With the help of this approach, the reviewer required less efforts and also save time reviewing data.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Name: Himanshu Patel
Enterprise: Merck & Co., Inc.
Address: 126 E. Lincoln Ave
City, State & Zip: Rahway, NJ 07065-4607
Phone: (732) 594-4071
E-mail: Himanshu.patel@merck.com
Web: www.merck.com

Name: Jeff Xia
Enterprise: Merck & Co., Inc.
Address: 126 E. Lincoln Ave
City, State & Zip: Rahway, NJ 07065-4607
Phone: (732) 594-6439
E-mail: jeff.xia@merck.com
Web: www.merck.com

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