



Patient Profiles

A Clinical Trial Software System

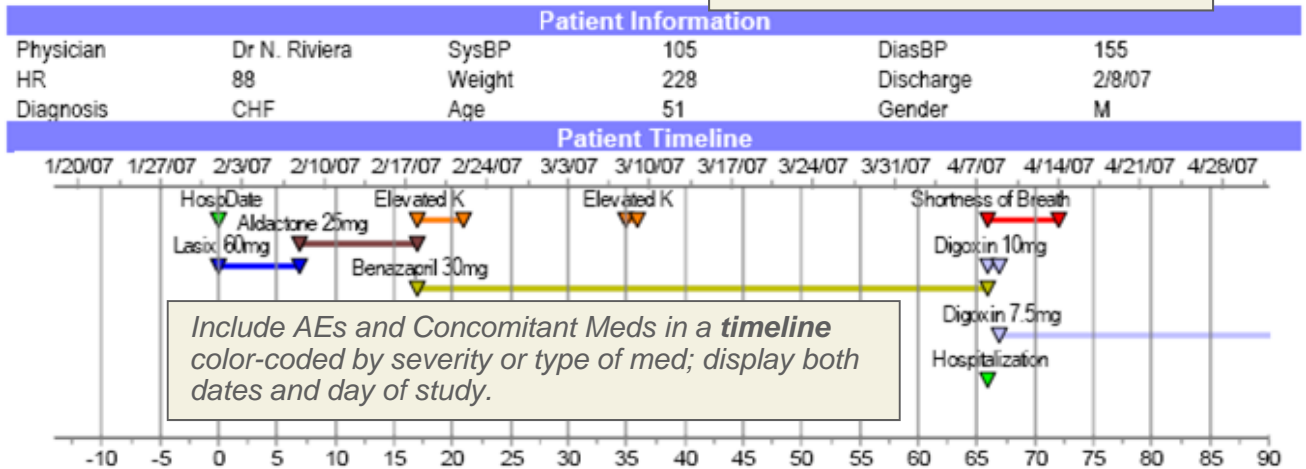
Flags

Patient ID 1

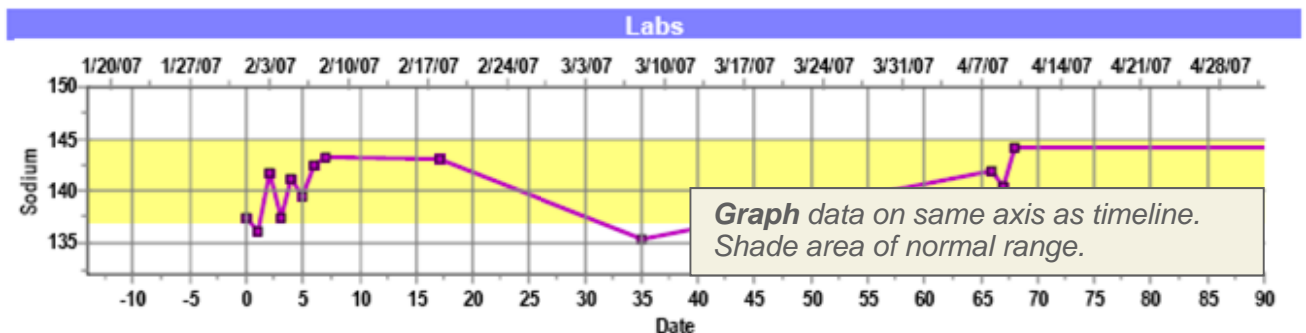
Na < 137

Flag extreme values exceeding defined thresholds.

Timeline



Graphs



Tables

Meds		
MedName	Date	EndDate
Lasix 60mg	2/1/07	2/8/07
Aldactone 25mg	2/8/07	2/18/07
Benazapril 30mg	2/18/07	4/8/07
Digoxin 10mg	4/8/07	4/9/07
Digoxin 7.5mg	4/9/07	

OtherEvents	
Event	Date
Hospitalization	4/8/07

Include details of events and other variables in tables.

AE Narrative

Serious Adverse Event Narrative

This case is a report referring to a 51 year old male subject (subject ID #1). An investigator reported this case from study 39 and center 5. Past medical history included diabetes. No allergies were reported. On February 1, the subject began treatment with Signia (5 mg BID). On April 8, 2007, the subject presented with severe shortness of breath (Dyspnea). Concomitant

Automatically generate Adverse Event Narratives.

Find Answers Quickly. Reduce Review Time.

Increase the efficiency of your teams.

Webviewer

Key features:

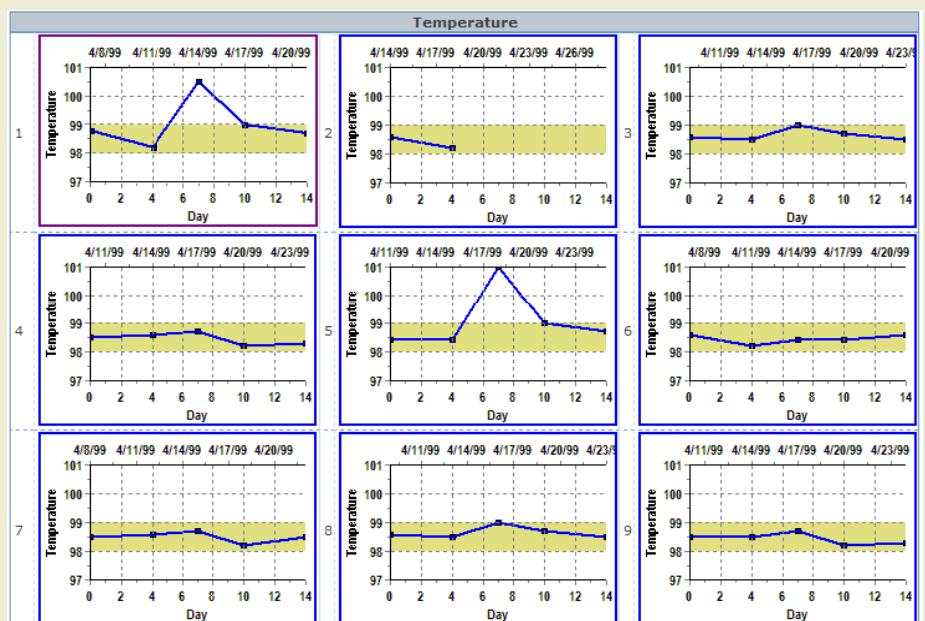
- Create a profile design in under an hour using the easy interface in Patient Profiles.
- Save your profiles as PDF or Microsoft Word files, or link them together in a "Webviewer".
- All the patient profiles from your trial are linked together with different ways to search, sort and filter in the webviewer.
- Key variables identified in the profile design are used in the webviewer for filtering options.
- Thresholds defined in the profile design (the "flags") are used in the webviewer to calculate the number of patients meeting certain criteria.

Patient Results At A Glance

Patients	Center Boston	Primary Site of Cancer Filter: All	Target Area (sq cm) Filter: All	Severe AE Filter: All
C01	Boston	Breast	185.25	
C03	Boston	Pelvic	270.3	■
C04	Boston	Breast	354.96	
C05	Boston	Head/Neck	256.1	■
C06	Boston	Breast	476	
C07	Boston	Breast	257.64	
C08	Boston	Pelvic	332.7	
C09	Boston	Breast	243.8	■
C10	Boston	Breast	273.1	■
C11	Boston	Breast	252	■
C12	Boston	Head/Neck	297	■
C13	Boston	Breast	288	■
C14	Boston	Head/Neck	180	
C15	Boston	Pelvic	529	■
C16	Boston	Breast	231	
15 of 33 patients match filter(s)				8 ■

Teams can quickly scan individual patient results, find patients of interest and easily monitor the total number of patients meeting criteria like Severe AE. Click a patient to view the patient's entire profile.

Timetrends Across Patients



Teams can browse through individual graphs for all patients. Outliers, missing data and unusual trends will stand-out. Click a graph to view the patient's profile.

Decrease the number of data requests.



www.PatientProfiles.com

Summary Statistics

Numeric Variables	Mean	SD	Min	Max
Age	61.18	12.53	42	83
Target Area (sq cm)	303.69	153.57	106.25	800

Categorical Variables			
Gender	N	Percent	
Female	27	82	<div style="width: 82%;"></div>
Male	6	18	<div style="width: 18%;"></div>
Race	N	Percent	
Caucasian	22	67	<div style="width: 67%;"></div>
Hispanic	7	21	<div style="width: 21%;"></div>
Black	3	9	<div style="width: 9%;"></div>
Asian	1	3	<div style="width: 3%;"></div>
Completed?	N	Percent	
Yes	31	94	<div style="width: 94%;"></div>
No	2	6	<div style="width: 6%;"></div>

Summary statistics are automatically calculated for all variables identified in the baseline/demographic section of the profile design.

Table Text Searches

Search:

Filter:

Patients	Adverse Events
A07	Infection - Other (Specify, folliculitis)
C03	Fatigue, Diarrhea NOS, Fatigue, Infection: Vagina, Fatigue, Diarrhea NOS (hyperglycemia), Fatigue, Infection: Urinary tract NOS
C07	Infection: Lip/perioral (unk ANC), Infection - Other (Specify, Viral Infe
C08	Fatigue, Diarrhea NOS, Abdominal pain NOS, Pain: Head/Headaches, My Skin, Neutrophil count, Platelet count decreased, Glucose, serum-high (hyperglycemia), Hemoglobin, Fatigue, Urinary frequency/urgency (Pol Other (Specify, folliculitis)
C09	Cough, Pain: Head/Headaches, Anorexia, Stomach discomfort, Fatigue, I muscle), Back Pain, Infection: Upper airway NOS, Fatigue, Peripheral se (Specify, Herpes Infection L axilla L breast), Fatigue, Infection: Urinary
C15	Abdominal pain NOS, Edema: limb, Diarrhea NOS, Abdominal pain NOS pain NOS, Infection: Urinary tract NOS, Dizziness, Tremor, Infection: Lu (pneumonia), Fatigue, Thrombosis/thrombus/embolism, Proctitis, Diarrh NOS, Thrombosis/thrombus/embolism, Edema: limb, Abdominal pain N
C16	Fatigue, Fatigue, Fatigue, Diarrhea NOS, Abdominal pain NOS, Infection - Head/Headaches

Text from individual patient tables in the profile design is compiled together to produce one large table with all events from all patients. Use the filter and highlight features to find patients who have certain events. In this example, the events are color-coded by severity.

Key features:

- The webviewer can be automatically refreshed with new data every day.
- The webviewer interface feels familiar the very first time you use it.
- SAS formats and labels can be imported to save you time and make your data more “readable”.
- Tables and graphs can be easily copied and pasted into other word processing or spreadsheet programs.

Try out the sort, search and filter functions yourself. Our example webviewer is at www.patientprofiles.com/WebViewer.htm

Give team members a tool to explore the data.

Find Answers Quickly

With the increasing use of electronic data capture, people expect instantaneous access to results from a clinical trial. Demands on data management teams and CROs have increased accordingly. With Patient Profiles you can create a study-specific tool that will enable all team members and clients to view and explore the data themselves. This will reduce review time and improve workflow between the CRO and the client.

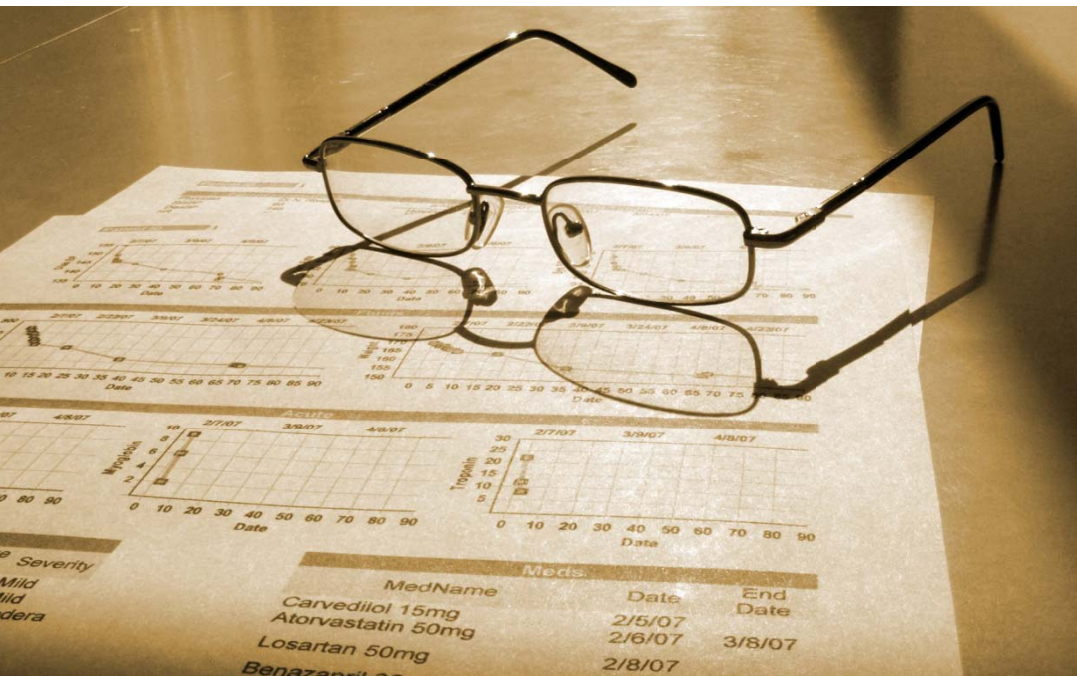
Explore Data Whenever, Wherever

A profile design is created at the beginning of a study using the easy point-and-click Patient Profiles interface. The program automatically saves the data from the profiles into a searchable web-based format. All team members can explore the data whenever, wherever they want. The "webviewer" is not connected to the database, nor is it reliant upon a software program to run. It is a stand-alone web-based system that can be opened using any internet browser. The Patient Profiles' design file can be scheduled to run automatically to update the webviewer as new data accrues.

Schedule a Demo For Your Trial

We will demo the program using your clinical trial data and provide the resulting webviewer to you for free. Contact us to schedule a demo today.

www.PatientProfiles.com



Patient Profiles

Technical Information

- Patient Profiles is windows-based. It accepts all types of data (Oracle, SAS, Excel, CDISC). No reformatting of data is necessary prior to import.
- Patient Profiles records all the data sources, calculations and definitions used to generate a profile. This information is saved in the XML profile design file and displayed in the webviewer.
- The webviewer is web-based. Information is stored in HTML text files, therefore no access to the data (or any software) is necessary to open it. The webviewers can be opened in Internet Explorer, Firefox and Safari.
- Patient Profiles was developed by Michael and Barbara Elashoff, formerly FDA reviewers.

Patient Profiles

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