



Target e*CRF[®]

Version 1.0

For more information,
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Target e*CRF[®] is a registered trademark of Target Health[®] Inc

Target e*CRF[®]

What Is It?

- Target e*CRF[®] is a web-based, proprietary, data and project management system designed for ease of use and high throughput. Target e*CRF[®] was developed by and has been used exclusively by Target Health Inc. since 1999. It is 100% accepted by sites, CRAs and sponsors. As a full service CRO representing over 25 companies at the FDA, we understand what it takes to run a trial. Target Health developed this software to streamline the process and optimize results.

How We Differ!

- Studies are generally built and deployed within 4 weeks
- Built in query management / edit check system with integration of SAS Batch Edit Check
 - Can import edit checks directly from SAS Client (or Monitor) can decide when edit checks are fired (upon data entry or batch)
- Provide system generated Randomization and drug management
- Training
 - Sites trained in less than one hour
 - CRAs trained in less than one hour
- Automatically provides E-mail notifications based on logic you define
- 100% accepted at sites
- Customized management reports
- Built in management reports
 - Data entry status
 - Patient profile
 - Query aging report
- Entire system (Study setup and configuration as well as data entry) can be run over dial up connection
- Manage protocol amendments in hours (NOT weeks)
- Modify edit checks in hours (NOT days)
- Manage patient enrollment
- For Sites:

- Allow sites to have more control
- They can register users
- Monitors can better manage sites

Benefits and Features

- Built in workflow enables intuitive set-up and execution
- Client can run in any environment
 - ASP hosted by Target Health
- Fast set up and training
- Proven
 - Over 130 studies completed
 - Over a dozen approved products on the market today which used Target e*CRF[®] for the pivotal trial(s)
- Elimination of traditional paper CRF's
- Minimization of data transcription and logic errors
- In most cases, clients lock database within 1 week of LPLV (last patient last visit)

Screens

Edit Check / Query Report: All Cases

ABC	PROTOCOL DEMOECRF : CLIENT IN-HOUSE MONITOR		19 May 2008	Ver 1.00	
PHARMACEUTICALS	MAIN	REGISTRATION	QUERY/EDIT CHECK	MANAGEMENT REPORTS	STATUS - BY SUBJECT

EDIT CHECK/QUERY REPORT: ALL CASES

Screening Number: **99S079** Subject Number: **9907** Initials: **AB**

Query #	Form Name	Field	Edit Check Details	Value	Entry Date	View Detail	Status
187	VITAL SIGNS, MOTHER (VISIT 1)	MATERNAL HEART RATE	Maternal heart rate (50) is not in the interval [56-120] bpm	50	6Jul2006 19:33	<input type="button" value="View"/>	Resolved - OK As Is (IF-J.MONITOR)
185	CONCOMITANT MEDICATION (CON.MED / AE)	MEDICATION ROUTE	Route is/are missing		6Jul2006 19:31	<input type="button" value="View"/>	Resolved - OK As Is (IF-J.MONITOR)
188	VITAL SIGNS, MOTHER (VISIT 1)	TEMPERATURE	Temperature (39) is not in the interval [36.0-37.5] Celsius	39	6Jul2006 19:33	<input type="button" value="View"/>	Resolved - Data Modified /Query Approved (IF-J.MONITOR)
186	CONCOMITANT MEDICATION (CON.MED / AE)	Start time	Start time and N/A are missing		6Jul2006 19:31	<input type="button" value="View"/>	Resolved - Data Modified /Query Approved (IF-J.MONITOR)

Please Click On the [View](#) to View the Details

Subject List

<table border="1"> <tr> <td>ABC</td> </tr> <tr> <td>PHARMACEUTICALS</td> </tr> </table>		ABC	PHARMACEUTICALS	PROTOCOL DEMOECRF : CLIENT IN-HOUSE MONITOR			19 May 2008 Ver 1.00			
ABC										
PHARMACEUTICALS										
<table border="1"> <tr> <td>MAIN</td> <td>REGISTRATION</td> <td>QUERY/EDIT CHECK</td> <td>MANAGEMENT REPORTS</td> <td>STATUS - BY SUBJECT</td> </tr> </table>		MAIN	REGISTRATION	QUERY/EDIT CHECK	MANAGEMENT REPORTS	STATUS - BY SUBJECT				
MAIN	REGISTRATION	QUERY/EDIT CHECK	MANAGEMENT REPORTS	STATUS - BY SUBJECT						
SUBJECT LIST (As of Monday, May 19, 2008, 12:16:34 PM)										
No	Site No.	Screening No.	Subject No.	# of Forms Entered	# of Pages Entered	# of Pages Reviewed In-Field	# of Pages Reviewed In-House	Subject Locked		
1	99	99S019 (JJ)	9917	6	6	2	2	NO		
2	99	99S029 (AA)	9901	13	14	1	0	NO		
3	99	99S039 (LS)	9906	6	7	3	1	YES		
4	99	99S049 (AA)	9910	5	5	3	0	NO		
5	99	99S059 (WW)	9905	7	7	1	0	NO		
6	99	99S069 (JY)		4	4	1	0	NO		
7	99	99S079 (AB)	9907	11	12	3	0	NO		
8	99	99S089 (AA)	9915	4	4	1	0	NO		
9	99	99S179 (WW)	9926	6	6	0	0	NO		
10	99	99S189 (LS)	9988	5	5	2	0	NO		
11	99	99S209 (TT)	9949	4	4	1	0	NO		
12	99	99S219 (JT)	9982	4	4	2	1	YES		
13	99	99S329 (LS)	9985	6	6	1	1	YES		
14	99	99S339 (ZZ)		2	2	0	0	NO		
15	99	99S359 (LS)	9987	4	4	1	0	NO		
16	99	99S459 (LS)	9945	6	6	1	0	YES		
17	99	99S559 (GL)	9997	7	7	0	0	NO		
18	99	99S579 (AB)	9956	5	5	1	0	NO		
19	99	99S609 (XX)	9981	2	2	0	0	NO		
20	99	99S769 (AB)	9983	4	4	1	1	YES		
21	99	99S809 (DD)	9955	6	6	3	0	NO		
22	99	99S839 (LS)		1	1	0	0	NO		
23	99	99S909 (IN)		5	5	1	0	NO		
24	99	99S929 (WW)		3	3	2	0	NO		
25	99	99S939 (CC)	9951	3	3	1	0	NO		
26	99	99S949 (QQ)		2	2	0	0	NO		
27	99	99S999 (TH)		4	4	0	0	NO		
Total:				135	138	32	6	5		

Please Click On the [Subject Number](#) to View the Available Forms and Descriptions

Investigator Signature Status Subject List

ABC PHARMACEUTICALS		PROTOCOL DEMOECRF : CLIENT IN-HOUSE MONITOR			19 May 2008 Ver 1.00		
MAIN		REGISTRATION		QUERY/EDIT CHECK		MANAGEMENT REPORTS	STATUS - BY SUBJECT

INVESTIGATOR SIGNATURE STATUS SUBJECT LIST
 (As of Monday, May 19, 2008, 12:17:12 PM)

No	Site No.	Screening No.	Subject No.	Signature	Signed By	Signed Date	Signed Time
1	99	99S019 (JJ)	9917	NO			
2	99	99S029 (AA)	9901	NO			
3	99	99S039 (LS)	9906	YES	TARZAN INVSTIGATOR	16 May 2006	09:14
4	99	99S049 (AA)	9910	NO			
5	99	99S059 (WW)	9905	NO			
6	99	99S069 (JY)		NO			
7	99	99S079 (AB)	9907	NO			
8	99	99S089 (AA)	9915	NO			
9	99	99S179 (WW)	9926	NO			
10	99	99S189 (LS)	9988	NO			
11	99	99S209 (TT)	9949	NO			
12	99	99S219 (JT)	9982	NO			
13	99	99S329 (LS)	9985	YES	TARZAN INVSTIGATOR	13 Feb 2008	11:51
14	99	99S339 (ZZ)		NO			
15	99	99S359 (LS)	9987	NO			
16	99	99S459 (LS)	9945	YES	TARZAN INVSTIGATOR	25 Oct 2007	12:33
17	99	99S559 (GL)	9997	NO			
18	99	99S579 (AB)	9956	NO			
19	99	99S609 (XX)	9981	NO			
20	99	99S769 (AB)	9983	NO			
21	99	99S809 (DD)	9955	NO			
22	99	99S839 (LS)		NO			
23	99	99S909 (IN)		NO			
24	99	99S929 (WW)		NO			
25	99	99S939 (CC)	9951	NO			
26	99	99S949 (QQ)		NO			
27	99	99S999 (TH)		NO			

Please Click On the [Subject Number](#) to View the Available Forms and Descriptions



Adverse Event Log (Con.Med / AE)

ABC
PHARMACEUTICALS

SITE
JOHN COORDINATOR

Site: 99

[BACK TO MAIN](#)
[CHANGE SUBJECT](#)

[VISIT 1](#)
[VISIT 2](#)
[RANDOMIZATION](#)
[VISIT 4](#)
[CON.MED / AE](#)
[END OF STUDY](#)

Protocol: DEMOECRF DEMO PROTOCOL DESCRIPTION
Screen #: 99S579 Subject #: 9956 Initials: AB Module/Tab: CON.MED / AE

[Con Med](#) [Adverse Event](#)

ADVERSE EVENT LOG (CON.MED / AE)

Adverse Event <input type="text"/>	
Date of Onset <input type="text"/> <input type="text"/> <input type="text"/> dd/mon/yyyy	N/A Time of Onset (24 hour format) <input type="checkbox"/> <input type="text"/>
Intensity	<input type="text"/>
Relation to study drug	<input type="text"/>
This AE is concerning	<input type="text"/>
Serious	<input type="text"/>
Any action taken (If Yes, please specify)	<input type="text"/>
Specify <input type="text"/>	
Date of Outcome <input type="text"/> <input type="text"/> <input type="text"/> dd/mon/yyyy	N/A Time of Outcome (24 hour format) <input type="checkbox"/> <input type="text"/>
Outcome	<input type="text"/>
<p>* Please complete a Serious Adverse Event Report Form and contact the Parexel Medical Safety Center (see instruction page) immediately.</p> <p>** Comment any action taken and if it was medication, please also enter in the Concomitant Medication log.</p> <p>*** If worsened, please complete a new Adverse Event log for the event.</p> <p>**** If not yet recovered at end of study and classified as either serious or severe or possibly or probably related to the study drug, please complete a Final outcome form.</p>	

[Submit](#) [Reset](#) [Save](#) [Go Back](#)

Inclusion Criteria at Screening (Visit 1)

ABC	Protocol: DEMOECRF	DEMO PROTOCOL DESCRIPTION							
PHARMACEUTICALS	Screen #: 99S579 Subject #: 9956 Initials: AB Module/Tab: VISIT 1								
SITE	Visit Date	Inclusion	Exclusion	Transvaginal Ultrasound	Demographics	Vital Signs Mother	Physical Exam Mother	Medical History	
JOHN COORDINATOR	INCLUSION CRITERIA AT SCREENING (VISIT 1)								
Site: 99	Please fill in below as you proceed with the examinations / assessments at screening.								
BACK TO MAIN	Has the Subject met any of the following inclusion criteria?							Yes	No
CHANGE SUBJECT	1. Signed Informed Consent Form, prior to screening evaluations							<input type="radio"/>	<input type="radio"/>
VISIT 1	2. Mother and fetus in good general health							<input type="radio"/>	<input type="radio"/>
VISIT 2	3. Pregnant woman with age \geq 18 years							<input type="radio"/>	<input type="radio"/>
RANDOMIZATION	4. Gestational age (verified by early ultrasound) between 34 weeks + 0 days and 35 weeks + 6 days (both days inclusive)							<input type="radio"/>	<input type="radio"/>
VISIT 4	<input type="button" value="Submit"/> <input type="button" value="Reset"/> <input type="button" value="Save"/>								
CON.MED / AE									
END OF STUDY									