



TARGET e*CRO

**TARGET HEALTH INC.
261 Madison Avenue, 24th Floor
New York, NY 10016
212-681-2100**

WWW.TARGETHEALTH.COM

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1. MISSION STATEMENT

Target Health Inc., a full service e*CRO, is committed to serve the pharmaceutical community through knowledge, experience, technology and connectivity. We strive to optimize the life cycle of drugs, biologics and devices with expertise, leadership, innovation and teamwork.

2. WHY DO COMPANIES WORK WITH TARGET HEALTH?

- Track Record of NDA and Other Regulatory Approvals
- In Business since 1993
- Drug/Device Development is Our Business
- We Are Not Just a Technology Company
- EDC (Target e*CRF®) since 1999 – 21 CFR Part 11 Compliant
- Experienced Management Team
- 50% of Employees 5+ Years at the Company
- Extensive Experience with FDA
- Broad Clinical Backgrounds
- Always Meet Deadlines
- Repeat Business From Our Clients
- We Measure Our Success By Your Success

3. TARGET HEALTH INC.

TARGET HEALTH INC. is a New York City based full service CRO with staff dedicated to all aspects of Regulatory Affairs, Clinical Research, Biostatistics, Data Management, Strategic Planning and Drug and Device Development. **TARGET HEALTH INC.** also has a group of specialized advisors in the areas of Toxicology, Analytical Methods Validation, Product and Process Development, Quality Assurance and Manufacturing. In addition, **TARGET** is committed to bridging Internet-based technology with the drug and device development processes.

TARGET HEALTH INC. submits approximately 3 INDs per year, 2-3 510(k)s and is currently involved with 10 active INDs and 2 active IDEs. **TARGET HEALTH INC.** clients include Fortune 100 companies as well as many smaller companies.

3.1 FDA Audit

In May 2008, FDA completed a 4 day, unannounced though not unexpected, inspection of Target Health for an NDA under review. For this program Target Health performed all of the clinical and regulatory strategic planning, toxicology, regulatory, study designs, monitoring of the clinical trials (Phase 1, 2 and 3), data management, including Target e*CRF® (EDC), statistics, medical writing and preparation of the NDA. There were 2 pivotal trials and a rescue protocol for treatment failures. The FDA audit also included a detailed review of Target e*CRF® and data management. The outcome of the inspection was as follows:

“This inspection is a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to ensure

that the rights, safety, and welfare of the human subjects of those studies have been protected.”

“From our evaluation of the establishment inspection report and the documents submitted with that report, we conclude that you adhered to the applicable statutory requirements and FDA regulations governing the monitoring practices of clinical investigations and the protection of human subjects.”

3.2 Approvals

We are very pleased to announce that there are now 30 marketed products that Target Health contributed to including 20 unique products (NDA/MAA-6; PMA-11; Canadian Device-1: BLA-1; and 510k-1) with marketing approval that used Target e*CRF® for their pivotal trials.

3.3 Target e*CRF® Regulatory Submissions – NDA – BLA – PMA

3.3.1 Approvals

There are now 21 products marketed world-wide that used Target e*CRF for their pivotal trials:

1. **MAA** – FIRAZYR (Shire/Jerini) EDC
2. **NDA** – ULESFIA - (Summers Laboratories, Inc./Sciele) – EDC; Monitoring; DM; Statistics; Writing; Toxicology; NDA (eCTD)
3. **NDA/MAA** - ellaOne® (HRA Pharma) EDC ; Monitoring; DM; Statistics; Writing
4. **NDA/MAA** - DEGARELIX - (Ferring Pharmaceuticals) –EDC
5. **BLA** – ARCALYST (Regeneron Pharmaceuticals) – EDC
6. **NDA/MAA** – MENOPUR (Ferring Pharmaceuticals) – EDC ; DM; Statistics
7. **NDA/MAA** – BRAVELLE (Ferring Pharmaceuticals) – EDC; DM; Statistics
8. **CANADIAN DEVICE** – AUGMENT™ Bone Graft (Biomimetic Therapeutics) – EDC
9. **PMA** – GEM 21S (Biomimetic Therapeutics) – EDC ; Monitoring; DM; Statistics; Writing
10. **PMA** – REPEL CV (Synthemed, Inc. Approved) – EDC ; Monitoring; DM; Statistics; Writing; PMA (eCopy)
11. **PMA** – **Ten (10)** Diagnostic Approvals (Abbott Laboratories) – EDC
12. **510(k)** – One (1) Diagnostic Approval (Abbott Laboratories) – EDC

3.3.2 Pending Approval

1. **NDA** Cystic Fibrosis – Submitted 2008 – Monitoring; DM; Statistics; Writing; NDA preparation
2. **NDA** Gaucher Disease - Submitted 2009 – Monitoring; DM; Statistics; Writing; NDA preparation

3.4 Orphan Product Designation - Approved

1. Alagille Syndrome
2. Caries prevention, head and neck cancer

3. Cushing's syndrome secondary to ectopic ACTH secretion
4. Edema-related effects in hospitalized patients with 3rd degree burns
5. Gaucher Disease
6. Hospitalized patients with 3rd degree burns
7. Hereditary angioedema
8. Osteonecrosis of the jaw
9. Scleroderma

3.5 510(k) Approved

1. Pregnancy Test
2. Keloid Scar Reduction (n=2)
3. Prophy Paste
4. Dental Cream (sensitive teeth)
5. Acupuncture Device
6. Parkinson's Disease Monitor
7. Male Contraception
8. Cardiac Diagnostic

3.6 Current Clients (Partial list)

- Abbott Diagnostics
- Anterios, Inc.
- Aposense, Ltd. (Israel)
- Argentis Pharmaceuticals
- BioCancell Therapeutics, (Israel)
- Biomimetic Therapeutics
- Cleveland Clinic
- Curetech, Ltd. (Israel)
- Devirex Ltd. (Switzerland)
- Digestive Care Inc.
- Eli Lilly and Co.
- Ferring Pharmaceuticals (Denmark, USA, UK)
- GalMed, Ltd (Israel)
- HRA Pharmaceuticals (France)
- Hill Top Research
- Infacare Pharmaceuticals
- Jerini, AG (Germany)
- Lifebond, LTD (Israel)
- Meditor Pharmaceuticals (Israel)
- Mediwound Ltd (Israel)
- Modigenetech, Ltd. (Israel)
- Morria Pharmaceuticals, Plc (England)
- Neomatrix, Inc.
- Pfizer Inc
- Phage Pharmaceuticals
- G. Pohl Boskamp (Germany)

- Progen Pharmaceuticals (Australia)
- Prometheus Laboratories
- Protalix Pharmaceuticals (Israel)
- Ready Clinical
- Regeneron Pharmaceuticals
- Rutgers University
- Samyang Pharmaceuticals (Korea)
- Se-Cure Pharmaceuticals Inc. (Israel)
- Serenity Pharmaceuticals
- SUNY Stony Brook School of Medicine
- Synthemed, Inc.
- Topaz Pharmaceuticals
- TransPharma, Ltd. (Israel)
- University of Massachusetts School of Medicine
- University of Washington School of Medicine
- Vicor Technologies, Inc.
- White Mountain Pharma

3.7 Current Indications

1. Diagnostics:
 - HIV
 - Cardiology
 - Hepatitis
 - Pre-eclampsia
2. Devices:
 - Periodontal disease
 - Bone fractures
 - Cardiac implant
 - Wound healing
 - Osteoporosis (combination drug/device)
3. Drugs:
 - 3rd degree burns
 - Advanced refractory solid tumors
 - Autoinflammatory diseases
 - Bladder cancer
 - Cancer diagnostics
 - Cardiology
 - Cystic fibrosis
 - Fibromyalgia
 - Gaucher's disease
 - Growth retardation
 - Hereditary angioedema
 - HIV

- Human head lice
- Infertility
- Jaundice prevention
- Liver cell transplantation
- Macular degeneration
- Nocturia
- Osteoarthritis
- Osteoporosis
- Ovarian cancer
- Pancreatic cancer
- Periodontal disease
- Prostate cancer
- Rheumatoid arthritis
- Scleroderma
- Small cell lung cancer
- Stroke
- Tumor imaging
- Ulcerative colitis

3.8 Products

3.8.1 Target Document®

1. Allows for an Internet-based Trial Master File (TMF) with eSignatures
2. User Friendly document management system
3. No software installed
4. Post, share, electronically sign, search, archive, etc. any electronic document
5. Users trained in less than 30 minutes
6. Can be used for any product where documents are shared and archived both within and outside of a business.

3.8.2 Target Encoder®

1. Full integration with Target e*CRF®
 - a. Used to code CRF terms to dictionaries (MedDRA, WHODRUG, etc.)
 - b. Web based – no software installed
 - c. Manually coded terms reside in user-defined dictionary and can be reused when identical term reappears

3.8.3 Target e*CTMS®

1. Full integration with Target e*CRF®
 - a. Study documents and timeline tracking
 - b. Documentation of all study personnel
 - c. Monitoring visits tracked
 - d. Reports available to all authorized users

3.8.4 Target e*Pharmacovigilance

1. Full integration with Target e*CRF®
 - a. Enter the data once
 - b. Form populated with data pulled from Target e*CRF
 - c. Medical monitor narrative entered within Target e*CRF
 - d. Generates FDA approved facsimile of MedWatch Form 3500A

3.8.5 Target Newsletter™

1. Full integration with Target e*CRF®
2. Enrollment status pulled from database
3. Communication module with multiple address lists

3.8.6 Target e*CRF®

Target e*CRF® is **TARGET**'s innovative eClinical trial software solution package.

Target e*CRF® is an Internet-based, proprietary, data and project management system created exclusively by **TARGET** to collect clinical trial data over the Internet. Operationally, data are entered and submitted directly to a remote central database through a web-based data entry interface. Benefits include real time data availability, elimination of traditional paper CRF books, and minimization of data transcription and logic errors.

Key Features

Key Features	
21 CRF Part 11 compliant to assure data integrity, data security and traceability.	Allows for electronic signatures and has date and time stamps for all data entry and data modifications (audit trail).
Is 100% developed and managed by TARGET.	Compatible with Sponsor's database structure and comes with data warehousing.
Is a configured application with a web user interface.	Runs on all computer systems.
Requires NO software installation and NO high speed internet connections.	Has project specific data entry screens.
Runs off regular modem phone lines.	Can provide pre-assigned patient randomization and pin numbers.

Key Features	
Is housed at a secure website with a real-time redundant off-site backup.	Utilizes secure encrypted communication.
Provides unique websites and domain name.	Has a sophisticated, though user-friendly, query management system.
Is fully compatible with SAS.	Can provide E-mail notifications.
Benefits include:	Has customer specific edit/logic checks.
1. real time data availability	Maintains an audit trail of all changes to the database once data have been submitted.
2. elimination of traditional paper CRFs	Has a friendly and easy to use navigation system.
3. Higher data quality	Has customer-specific management reports.

The following summarizes the tasks which are either eliminated or are included when Internet data collection is performed. Other capabilities are also highlighted.

Task	Description
CRF Preparation	The CRF is prepared directly on the web. Only mockups are needed
CRF Printing	There is no need for commercial photocopying.
Retrieve CRF	Both the site and sponsor can immediately access the CRF upon data entry. There is no need to collect CRFs.
Data Entry	Since this task is performed by the site, there is also no need for double-key entry and related tasks such as SAS "data compare" between two databases.
In-House Data QA	Source document review occurs at the site and is included in the monitoring task. There is no in-house review of data entry against the CRFs.
On Site CRF Review	The CRF can be reviewed prior to the monitoring visit and questions sent via query management.
Edit Check Checks	There is no need for most of the usual SAS generated edit checks. Most edit and logic checks occur at the time of data entry and during the batch edit check process.
Database Design	Included
Audit Trail of Changes To The Database	Included and available in "real" time.
Query Resolution	All queries are automated with an electronic trail.
Statistical Analysis	The database is mapped for seamless integration with SAS®.

3.8.7 Target e*CRF Project List

	Indication	Phase	# of Sites	# of Patients
1	3rd degree burns	1	1	30
2	3rd degree burns	2	1	16
3	3rd degree burns	3	20	152
4	3rd degree burns	2	1	30
5	Acute Coronary Syndrome	Pivotal	6	750
6	Angioedema	4	20	120
7	Anovulation	3	22	186
8	Anovulation	3	26	180
9	Autoinflammatory	2	1	15
10	Autoinflammatory Syndromes	2/3	25	60
11	Bone fractures	Pilot	5	60
12	Bone fractures	Pivotal	18	280
13	Bone fractures	Pivotal	10	100
14	Bone fractures	4	3	25
15	Cardiac Diagnostic	3	6	700
16	Cardiac surgery - newborn	Pivotal	13	150
17	Cardiovascular / Hypertension	4	11	19
18	Chlamydia Trachomatis/Gonorrhoeae	Pivotal	7	2,250
19	Chronic Active Gouty Arthritis	5	5	10
20	Controlled Endstage Renal Disease	1	1	6
21	Coronary Artery Disease	2A	5	100
22	Delay of imminent preterm birth	2	6	9
23	Diabetes Insipidus. Enuresis nocturna. Nocturia	1	1	39
24	Diabetes Insipidus. Enuresis nocturna. Nocturia	1	1	122
25	Diabetes Insipidus. Enuresis nocturna. Nocturia	1	1	41
26	Diabetic Macular Edema	1	2	24
27	Emergency Contraception	3	37	1320
28	Emergency Contraception	3	7	2044
29	Enuresis nocturna	2/3B	7	101
30	Epilepsy	3	34	156
31	Gaucher's Disease	3	20	30
32	Head Lice	2	1	40
33	Head Lice	3	1	80
34	Head Lice	2	1	60
35	Head Lice	3	5	120
36	Head Lice	1	1	240
37	Head Lice	3	5	120

	Indication	Phase	# of Sites	# of Patients
38	Head Lice	3	10	200
39	Hepatitis	1	4	5,520
40	Hereditary Angioedema (HAE)	4	17	121
41	Hypotension	2	1	70
42	HIV & Hepatitis	Pivotal	10	5,500
43	Hyperbilirubinemia	1	4	2000
44	Hyperbilirubinemia	2	4	6,400
45	In vitro Fertilization (IVF)	3	30	660
46	In vitro Fertilization (IVF)	3	15	200
47	In vitro Fertilization (IVF)	3	8	33
48	In vitro Fertilization (IVF)	4	15	158
49	In vitro Fertilization (IVF)	4	14	151
50	In vitro Fertilization (IVF)	3	13	131
51	In vitro Fertilization (IVF)	Post Marketing	30	300
52	Jaundice	2	7	160
53	Juvenile idiopathic arthritis	3	8	18
54	Juvenile idiopathic arthritis	3	15	86
55	Macular Degeneration	1/2	10	60
56	Macular Degeneration	2	35	225
57	Menopausal syndrome	4	333	958
58	Migraine	2	20	523
59	Obesity	2A	5	100
60	Osteoarthritis of the Knee	2	12	160
61	Ovulation Induction	3	15	125
62	Pancreatic Cancer	2	13	43
63	Periodontal Disease	Post Marketing	1	8
64	Periodontal Disease	Post Marketing	1	5
65	Periodontal Disease	Post Marketing	1	10
66	Periodontal Disease	Post Marketing	1	9
67	Periodontal Disease	Pivotal	13	210
68	Periodontal Disease	Pivotal	9	130
69	PK	1	2	20
70	PK/PD	1	1	23
71	PK/PD	1	1	22
72	PK/PD	1	1	45
73	PK/PD	1	1	18
74	Polymyalgia rheumatica	2A	12	40

	Indication	Phase	# of Sites	# of Patients
75	Preeclampsia	Pivotal	6	4,000
76	Primary Nocturnal Enuresis	2/3	30	345
77	Prostate Cancer	1	1	97
78	Prostate Cancer	2	20	149
79	Prostate Cancer	2	12	34
80	Prostate Cancer	2	30	210
81	Prostate Cancer	2B	16	60
82	Prostate Cancer	1	1	61
83	Prostate Cancer	2/3	40	225
84	Prostate Cancer	2/3	45	160
85	Prostate Cancer	2/3	70	450
86	Prostate Cancer	2B	40	225
87	Prostate Cancer	2/3	45	160
88	Prostate Cancer	2/3	40	150
89	Prostate Cancer	3	140	675
90	Prostate Cancer	3	80	600
91	Public Health	4	1	400
92	Public Health	4	1	292
93	Rheumatoid Arthritis	2B	75	600
94	Rheumatoid Arthritis	2	5	50
95	Rheumatoid Arthritis	2	4	25
96	Treatment of Periodontal Bone Defects	Post Marketing	1	32
97	Ulcerative colitis	2	20	200
98	Ulcerative colitis	3	35	360
99	Women's Health Safety study	4	11	130
100	Women's Health Safety study	2	3	80
101	Wound healing	2	1	24
			1802	44,021

3.9 Capabilities

3.9.1 Regulatory Affairs

- Meet with the FDA to discuss and negotiate development strategies
- Plan international drug development strategies and registrations
- Prepare and submit:
 - a. Pre-IND/IDE briefing documents
 - b. IND and IND amendments
 - c. IDE
 - d. 510(k)
 - e. NDA

- f. PMA
- g. DMF
- h. Orphan drug designation requests
- Interact with legal counsel
- Assure that user-fee monies are submitted on schedule
- Follow up with FDA on post-NDA submission questions
- Perform pre-inspection GMP audits
- Support responses to FDA questions and warning letters
- Adverse event monitoring and reporting

3.9.2 Clinical Research

- Prepare protocols, case report forms and informed consent forms
- Perform qualification, initiation, monitoring and closeout visits
- Generate investigator study files
- Monitor drug supply
- Identify study sites and manage investigator payments
- Prepare clinical sites for FDA inspection
- Perform Quality Assurance audits

3.9.3 Medical Writing

- Write integrated clinical and statistical study reports and other regulatory manuscripts
- Orphan drug designation requests
- eCTD Submissions
 - a. IND
 - b. NDA

3.9.4 Biostatistics and Data Processing

- Target e*CRF® Internet-based data collection and project management
- Calculate sample size
- Generate randomization codes
- Generate database, perform data entry and QA
- Perform statistical analyses using Statistical Analysis System (SAS®)
- Prepare electronic files, with documentation, in SAS®

3.9.5 Product and Process Development

- Perform product and process development and optimization
- Production of clinical supplies under cGMP
- Arrange for drug supply packaging and labeling
- Perform analytical methods development and validation
- Troubleshoot product and process issues
- Identify contract manufacturers for product commercialization

3.9.6 Toxicology

- Design and implement toxicology programs to support clinical safety and regulatory requirements

3.9.7 Strategic Planning

- Work closely with the sponsor, medical, scientific, toxicology, manufacturing and business experts to clearly delineate development and regulatory requirements with a philosophy of efficiency and expediency
- Evaluate available and competitive technologies