



# **TARGET e\*CRO**

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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, Chemistry, Manufacturing and controls, Clinical Research, Biostatistics, Data Management and Strategic Planning. **TARGET HEALTH INC.** also has a group of specialized advisors in the areas of Toxicology, Analytical Methods Validation, and Product and Process Development.

**TARGET HEALTH** is committed to bridging Internet-based technology with the drug and device development processes.

**TARGET HEALTH INC.** submits approximately 3 INDs per year, 3-4 510(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.

## 4. FDA INSPECTION

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 that ***“from 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.”***

The sponsor had a perfect audit with no findings. We assisted each site as well as the sponsor for the FDA audits.

## 5. REGULATORY APPROVALS

***We are very pleased to announce that there are now over 27 marketed products that Target Health contributed to, including 18 unique products with regulatory marketing approval that used Target e\*CRF® for their pivotal trials. Target e\*CRF® is 21 CFR Part 11 Compliant.***

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

### 5.1 Pending Approvals

1. **NDA** - Cystic Fibrosis – Submitted 2008 – Monitoring; DM; Statistics; Writing; NDA preparation
2. **NDA** - Emergency Contraception – Submitted 2009 – EDC ; Monitoring; DM; Statistics; Writing
3. **NDA** – Gaucher Disease Submitted 2009 – EDC ; Monitoring; DM; Statistics; Writing, NDA Submission

### 5.2 ORPHAN PRODUCT DESIGNATION

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's disease
6. Hospitalized patients with 3rd degree burns
7. Hereditary angioedema
8. Osteonecrosis of the jaw
9. Scleroderma (US and Europe)

### 5.3 510(k)

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 algorithm

## **6. CAPABILITIES**

### **6.1 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

#### **6.1.1 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

#### **6.1.2 Medical Writing**

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

#### **6.1.3 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®

#### 6.1.4 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

#### 6.1.5 Toxicology

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

#### 6.1.6 Quality Assurance

- Perform GMP and GLP site audits
- Perform pre-approval inspection audits
- Prepare SOPs
- Prepare companies for regulatory audits

#### 6.1.7 Strategic Planning and Licensing

- 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

## 7. TARGET SOFTWARE

### 7.1 Target e\*CRF®

Target e\*CRF®, a 21 CFR Part 11 Compliant software, has now been used in over 160 clinical trial since 1999. Largest trial to date is over 7,000 patients. There are now 17 Approved Products in the US, Canada and Europe, that used Target e\*CRF® for their clinical trial programs (4-NDAs, 1 MAA, 1-BLA, 10-PMAs and 1-510(k)). This coming year, an NDA will be submitted in the area of Women's Health as well as an NDA for an Orphan Metabolic Disease. For the latter project, Target Health will also be preparing and submitting the eCTD.

### 7.1.1 Target e\*CRF Partial 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

	Indication	Phase	# of Sites	# of Patients
35	Head Lice	3	5	120
36	Head Lice	1	1	240
37	Head Lice	3	5	120
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

	Indication	Phase	# of Sites	# of Patients
72	PK/PD	1	1	45
73	PK/PD	1	1	18
74	Polymyalgia rheumatica	2A	12	40
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	3	35	360
98	Women's Health Safety study	4	11	130
99	Women's Health Safety study	2	3	80
100	Wound healing	2	1	24
			<b>1,770</b>	<b>43,821</b>

## 7.2 Target Document®

Target Document is a USER-FRIENDLY, COST-EFFECTIVE, HIGHLY SOPHISTICATED, Web-based, document management system that allows authorized users to view, download, and manage any document for their organization. - No More paper - Target Document features include: 1) 21 CFR Part 11 compliance; 2) routing for electronic signatures; 3) email alerts; 5) communication tools.

### **7.3 Target Encoder®**

Target Encoder is a USER-FRIENDLY, COST-EFFECTIVE, HIGHLY SOPHISTICATED, Web-based, coding system that allows authorized users to automatically code MedDRA and WHO Drug and other types of dictionaries. Target Encoder is fully integrated with Target e\*CRF.

### **7.4 Target e\*CTMS™**

Target e\*CTMS is a USER-FRIENDLY, COST-EFFECTIVE, HIGHLY SOPHISTICATED, Web-based, clinical trial management system. A new clinical trial starts with identification of the sponsor and project name. Investigators, IRBs and users are maintained within the CTMS and can be easily assigned to a project. All staff within a clinical site can be identified with their title and contact information, as well as shipping addresses which could be different from the head office. As the site commits to participate in the clinical trial, a site number can be assigned. Once IRB approval is obtained, and all regulatory documents have been identified as received, an alert can be sent out via email to allow for drug shipment. Target e\*CTMS provides many additional features such as: 1) Decision Logs, 2) Meeting Logs with uploading of the meeting minutes, 3) Questions and Answers, 4) status of Regulatory Submissions and Deliverables, and 5) Monitor Site Visit Tracking with document upload.

### **7.5 Target Batch Edit Checks**

With Target e\*CRF®, batch edit checks are now integrated with the electronic query system within the study. Target e\*CRF® runs the edits and displays the results of those edits through a discrepancy review screen integrated with the query system.

### **7.6 Target e\*Pharmacovigilance™**

Target e\*CRF integrates EDC with a pharmacovigilance module by 1) allowing the principle investigators to enter a narrative, 2) allowing the medical monitor to enter a narrative and then have the EDC system generate an approved version of Form 3500A or CIOMS for regulatory submission with the ability to control the original and followup submissions.

### **7.7 Target e\*Clinical Trial Record (Target e\*CTR™)**

Target e\*Clinical Trial Record (Target e\*CTR™) - The Electronic Medical Record for Clinical Trials™

Target e\*CTR allows the clinical study sites to perform direct data entry into any EDC system, and at the same time generates a read-only electronic document, which can be designated as the primary source data (eSource). These data, maintained in a secure, read-only trusted 3<sup>rd</sup> party environment, are available to the clinical study sites, monitors and regulatory agencies in a human readable format.

## **8. PARTIAL LIST OF ACCOMPLISHMENTS**

### **8.1 Chemistry, Manufacturing and Controls**

1. Audited multiple manufacturing plants to assure compliance with GMP including drug substances and parenteral, solid and topical dosage forms.
2. Prepared CMC section for IND submission for master and working cell banks for transformed carrot cells used to make an enzyme for enzyme replacement therapy.
3. Regulatory agent for a company that uses autologous cells for cartilage replacement to treat knee defects.
4. Prepared parenteral drug for the treatment of patient with HIV (CD4 <200).
5. Preparation of multiple IND CMC sections
6. Preparation of NDA CMC sections

### **8.2 Regulatory Submissions**

1. **IND:** Cardiology, Hereditary Angioedema, Gaucher's Disease, Male and Female Sexual Dysfunction, Pancreatic Cancer, Ophthalmology, Dermatology (3<sup>rd</sup> degree burns, hair growth, acne, head lice), Oral Care, Antiinfectives (AIDS), Cholesterol Lowering Agent, Infertility, Ulcerative colitis, Cushing's disease
2. **IDE:** Home Use NST, OB/GYN and Cardiovascular Anti-Adhesion Devices, Osteoporosis

### **8.3 FDA Meetings**

Bioterrorism, Stroke, Strategic Planning (Oral Care); Pre-IND (Cardiology, Neurology, Dermatology, Hereditary Angioedema, Gaucher's Disease, Osteoporosis, Cholesterol Lowering, Oral Care, Oncology, Sexual Dysfunction, Pulmonary, Rheumatology); Pre-IDE (Prostate Cancer, Adhesion Prevention – Gynecology/Cardiology, Wound Healing, High Risk Pregnancy, Cancer Diagnostic); End of Phase 2 (Oral Care, Cystic Fibrosis, Alagille Syndrome, Ophthalmology); Pre-NDA (Infertility, Dermatology)

### **8.4 Clinical Research - Phases 1 – 4**

AIDS, Anti-Adhesion (gynecology, cardiology), COPD Radiopharmaceutic, Cystic Fibrosis, Dermatology (acne, head lice, hair growth), Gaucher Disease, Gout, Hereditary Angioedema, Imaging agent, Oral Care, Oncology, Ophthalmology, Male and Female Sexual Dysfunction, Fetal Monitoring (NST), Pregnancy Diagnostic, Rheumatoid Arthritis, Ulcerative Colitis.

### **8.5 Medical Writing**

AIDS, Anti-Adhesion (gynecology, cardiology), Antidepressants, Antiinfectives, Cardiology, Gout, Cystic Fibrosis, Dermatology (acne, head lice, hair growth), Hereditary Angioedema, Oncology, Ophthalmology, Oral Care, Osteoarthritis, Osteoporosis, Rheumatoid Arthritis, Sexual Dysfunction, Ulcerative colitis.

## **9. INDICATIONS**

1. Diagnostics:
  - HIV
  - Cardiology
  - Hepatitis
  - Pre-eclampsia
2. Devices:
  - Periodontal disease
  - Bone fractures
  - Cardiac implant
  - Wound healing
  - Osteoporosis (combination drug/device)
3. Drugs:
  - 3<sup>rd</sup> degree burns
  - Atopic dermatitis
  - Autoinflammatory diseases
  - Cystic fibrosis
  - Emergency contraception
  - Fibromyalgia
  - Gaucher disease
  - Hereditary angioedema
  - Human head lice
  - Hypotension
  - Imaging
  - Infertility
  - Jaundice prevention
  - Juvenile rheumatoid arthritis
  - Liver disease
  - Macular degeneration
  - Nocturia
  - Osteoarthritis
  - Osteoporosis
  - Pancreatic cancer
  - Periodontal disease
  - Prostate cancer
  - Public health
  - Rheumatoid arthritis
  - Scleroderma
  - Small cell lung cancer
  - Stroke
  - Ulcerative colitis
  - Wrinkles

## **10. CLIENTS (PARTIAL LIST)**

- Abbott Laboratories, USA
- Alulim Inc., USA
- Anterios, Inc. USA

- Aposense, Ltd., Israel
- Argentis, LLC, USA
- Biomimetic Pharmaceuticals, USA
- Children's Hospital and Regional Medical Center (NIH Grant), USA
- Cleveland Clinic, USA
- Curetech, Ltd, Israel
- Cytodyn, Inc., USA
- Devirex, Ltd, Switzerland
- Digestive Care Inc., USA
- Embil Pharmaceuticals, Turkey
- Enzymotec, Israel
- ExSAR Corporation, USA
- Ferring Pharmaceuticals, Denmark/Holland / USA
- Foamix, Ltd, Israel
- Hill Top Research, USA
- HRA Pharmaceuticals, France
- Infacare Pharmaceuticals, USA
- Keraderm, Corp, USA
- Lifebond, Ltd. Israel
- Luitpold Pharmaceuticals, USA
- Mediwound Ltd., Israel
- Meditor Ltd., Israel
- Modigenetech, Ltd., Israel
- Morria Pharmaceuticals, England
- Natrogen Inc., USA
- Neurotune, AG, Switzerland
- Obecure, Ltd. Israel
- Pohl Boskamp, AG, Germany
- Prometheus Laboratories, USA
- Protalix, Ltd., Israel
- Regeneron Pharmaceuticals, USA
- Samyang Pharmaceuticals, Korea
- Se-Cure Pharmaceuticals, Israel
- Serenity Pharmaceuticals, USA
- Shire Pharmaceuticals
- Signum Biosciences, USA
- SUNY Stony Brook
- Synthemed, Inc., USA

- Thrombotech, LTD, Israel
- TNI, Inc
- TransPharma, Ltd., Israel
- University of Washington (NIH Grant)
- Vicor Technologies, Inc., USA
- White Mountain Pharma, USA

## **11. CONTACT INFORMATION**

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