

Click on Study from the Research Data under Access Data tab

The screenshot shows the ImmPort website interface. At the top, the 'Access Data' menu is open, with 'Studies' highlighted. Below the menu, there is a search options section with various filters. The main content area displays a table of study details. A callout box points to an ellipsis link in the table, indicating that it displays a list of study titles.

Search Options

Study: Accession Like
 Study Title Like
 Study Description Like
 Study Objectives Like
 Study: Project Equal
 Study Type Like

Study Details Table

Title	Principal Investigator	Objectives	Schematic	Start Date	End Date	Study Type	Subjects Number	Assay Result
<input type="checkbox"/> Allergen immunotherapy Co-administered with Omalizumab	Thomas Casale	Primary Objective: To examine whether omalizumab given prior to RIT followed by 12 weeks of dual oma...		2003-04-01		Interventional	159	ELISA FCM
<input type="checkbox"/> Immune Response to Varicella Vaccination in Subjects with Atopic Dermatitis Compared to Nonatopic Controls	Lynda Schneider	Primary Objective: To determine if children with AD have VZV-specific cell mediated immune (CMI) res...				Observational		FCM
<input type="checkbox"/> TEST STUDY 2 - PILOT - Allergen immunotherapy Co-administered with Omalizumab		Primary Objective: To examine whether omalizumab given prior to RIT followed by 12 weeks of dual oma...		2003-04-01		Interventional	159	ELISA FCM

Search based on results characteristics

Research Data / Study Summary  Selected Projects Change Projects

Home | Studies | Experiments | Subjects | Biological Samples | Protocols | Reagents | Experiment Sample | Uploaded Files | Share Research Data | Download Project Summary | Advanced Search

This page provides a summary overview of various types of clinical studies within your given research project. You may view detailed information about specific clinical study by selecting one or more studies and clicking the 'View Details' button.

Search Options

Study Title	Like	▼	...
Study Description	Like	▼	
Study Objectives	Like	▼	
Study: Project	Equal	▼	
Study Type	Like	▼	...

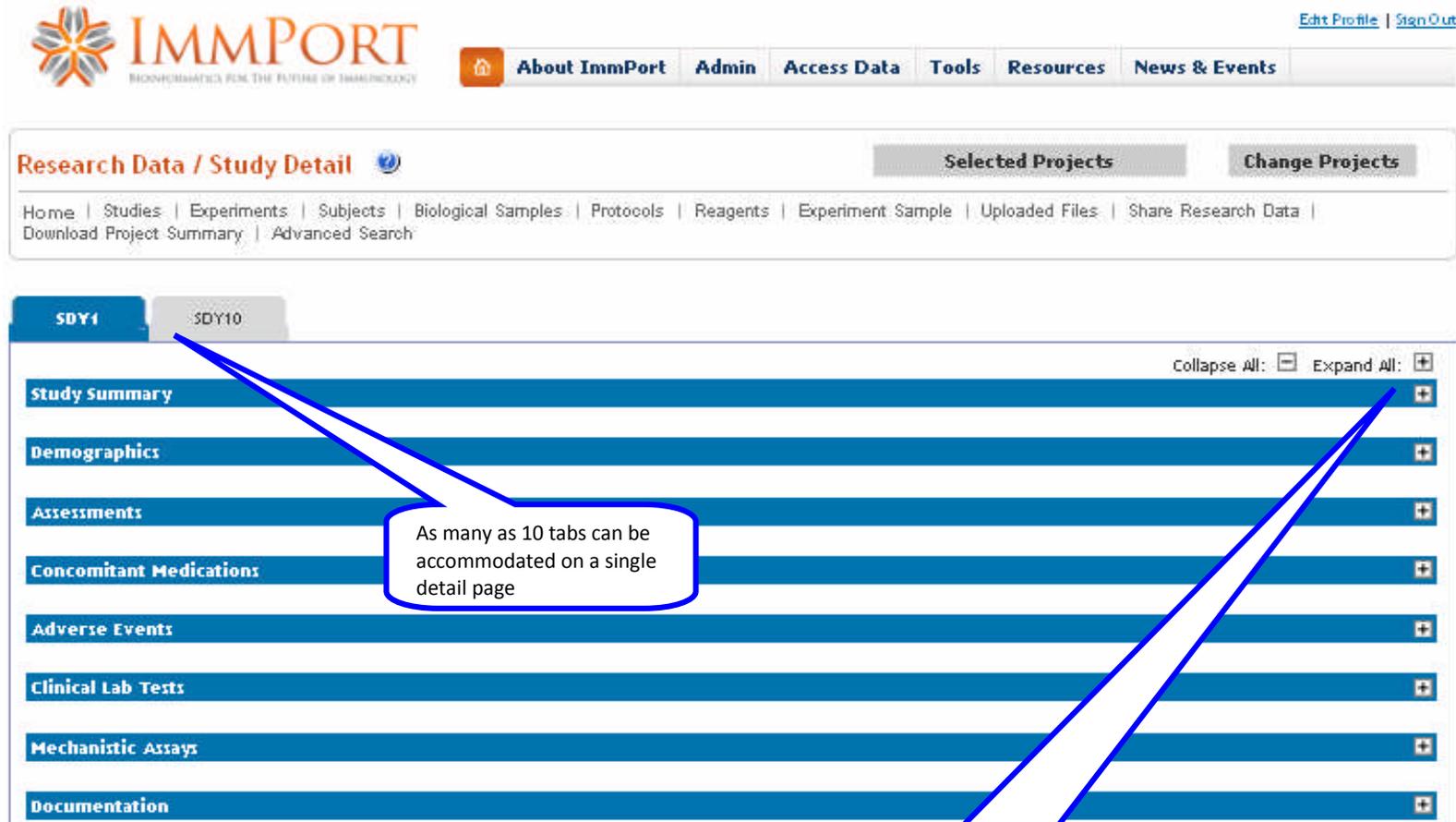
Study summary displays the study title, PI, objectives, schematics, date generated, study type, subjects number and the array result. Click on 'View details' or 'export' selected study for more details

Selected items: SDY1, SDY10

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<input type="checkbox"/>	Title	Principal Investigator	Objectives	Schematic	Start Date	End Date	Study Type	Subjects Number	Assay Result
<input checked="" type="checkbox"/>	Allergen immunotherapy Co-administered with Omalizumab	Thomas Casale	Primary Objective: To examine whether omalizumab given prior to RIT followed by 12 ...		2003-04-01		Interventional	159	ELISA FCM
<input checked="" type="checkbox"/>	Role of Antimicrobial Peptides in Host Defense Against Vaccinia Virus	Donald Leung	Primary Objectives: 1. To compare the levels of vaccinia virus gene expression in vaccin...		2005-06-01		Observational	286	
<input type="checkbox"/>	Genetics of Atopic Dermatitis - Eczema Herpeticum	Lisa Beck, Kathleen Barnes	Primary Objective: 1. To identify candidate genes relevant in AD subjects with...		2006-05-11		Observational		

Study detail page can be expanded to view detailed information of each block.



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Research Data / Study Detail 

Selected Projects **Change Projects**

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SDY1 **SDY10**

Study Summary 

Demographics 

Assessments 

Concomitant Medications 

Adverse Events 

Clinical Lab Tests 

Mechanistic Assays 

Documentation 

Collapse All:  Expand All: 

As many as 10 tabs can be accommodated on a single detail page

Expand each one of the blocks for more detailed information as seen in next slides

[\(Back to Advanced Search\)](#)

SDY1

Study Summary Block

Collapse All: Expand All:

Study Summary

Study Title: Allergen immunotherapy Co-administered with Omalizumab
 Study PI: Thomas Casale
 Study Type: Interventional
 Condition Studied: Seasonal allergy to ragweed
 Brief Description: A series of allergy shots may reduce symptoms of seasonal ragweed allergies. This study will determine whether taking a drug called omalizumab (also known as Xolair) before getting the allergy shots is more effective than allergy shots alone or other treatments, such as prescription antihistamines.
 Start Date: 2003-04-01
 Schematic: [Schematic Image \(!\[\]\(b29945fa2a6be561a89902fe3bc1eee0_img.jpg\) \)](#)
 Detailed Description: [Allergic rhinitis affects 20 to 40% of the American population. It is a chronic condition that can be managed ...](#)
 Objectives: **Primary Objective:** [To examine whether omalizumab given prior to immunotherapy can reduce the severity of allergic reactions.](#)
 Endpoints: **Primary Endpoint:** [The primary endpoint will be the average daily allergy severity score.](#)
 Gender Included: Both
 Subjects Number: 159
 Study Summary: [Download Study Summary](#)

Arms or Cohorts

Arm Name	Description	Population Selection Rule
ARM 1 Immunotherapy with anti-IgE	Omalizumab pre-treatment, ragweed RIT, omalizumab + ragweed IT	Randomized 1:1:1:1 to 4 treatment groups
ARM 2 Placebo Immunotherapy with anti-IgE	Omalizumab pre-treatment, placebo RIT, omalizumab + placebo IT	Randomized 1:1:1:1 to 4 treatment groups
ARM 3 Immunotherapy with placebo anti-IgE	Placebo omalizumab pre-treatment, ragweed RIT, placebo omalizumab + ragweed IT	Randomized 1:1:1:1 to 4 treatment groups
ARM 4 Placebo Immunotherapy with placebo anti-IgE	Placebo omalizumab pre-treatment, placebo RIT, placebo omalizumab + placebo IT	Randomized 1:1:1:1 to 4 treatment groups

Publications

PubMed ID	Year	Title	Journal	Authors
16387596	2006	Omalizumab pretreatment decreases acute reactions after rush immunotherapy for ragweed-induced seasonal allergic rhinitis	The Journal of Allergy and Clinical Immunology	Casale TB, Busse WW, Kline JN, Ballas ZK, Moss MH, Townley RG, Mokhtarani M, Seyfert-Margolis V, Asare A, Bateman K, Deniz Y; Immune Tolerance Network Group.
17631952	2007	Combination treatment with omalizumab and rush immunotherapy for ragweed-induced allergic rhinitis: Inhibition of IgE-facilitated allergen binding	The Journal of Allergy and Clinical Immunology	Klunker S, Saggari LR, Seyfert-Margolis V, Asare AL, Casale TB, Durham SR, Francis JN

Click here to download the study summary

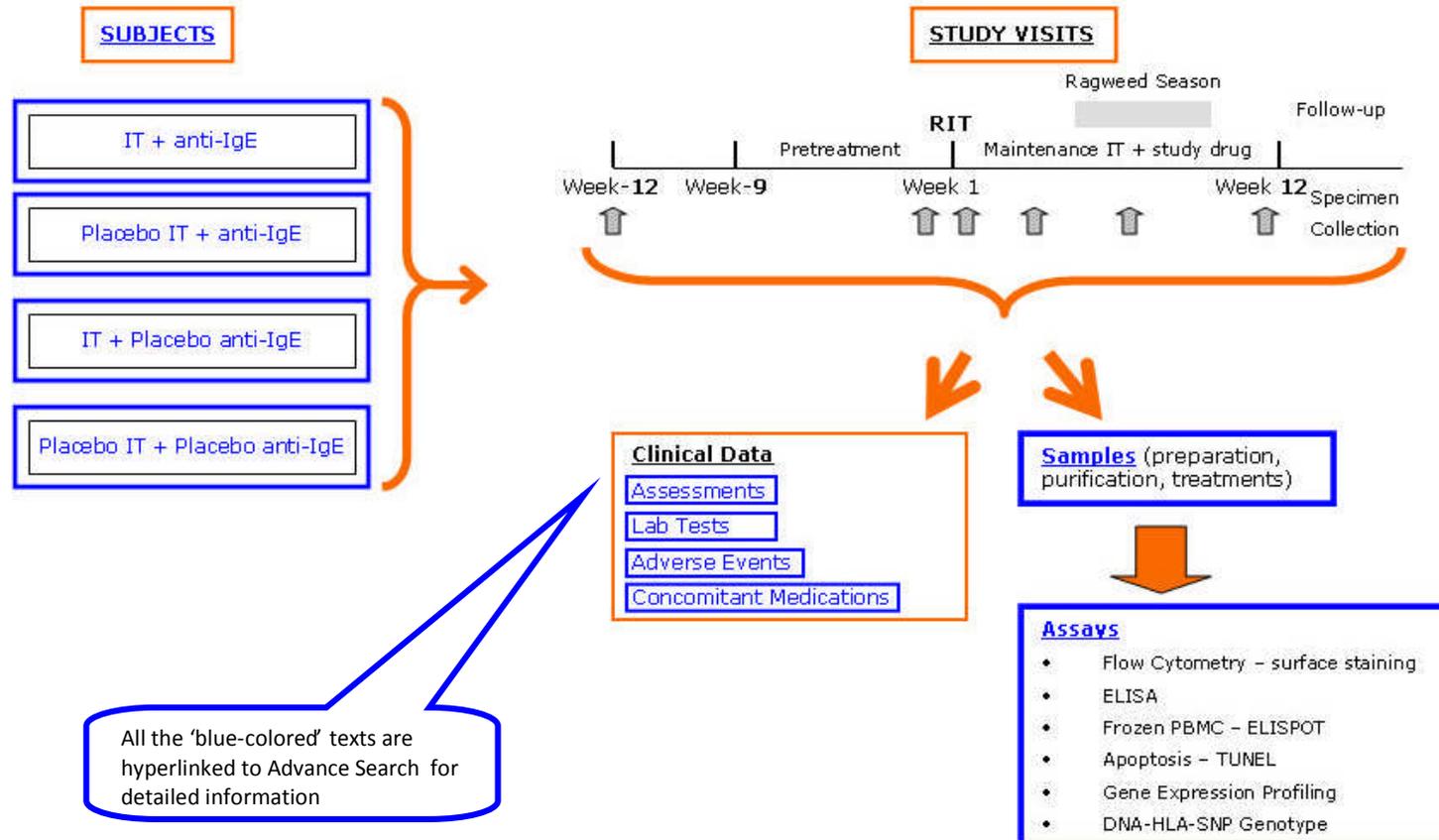
The schematic image is a graphic representation of the study.

The hyperlinks on this page can be clicked for more detailed information

The schematic is an overview of the project indicating the subjects used, the different clinical data obtained, the samples used as well as the mechanistic assays and results.

Title: Efficacy and Safety Evaluation of Allergen Immunotherapy Co-Administered with Omalizumab, an anti-IgE Monoclonal Antibody.
PI: Thomas B. Casale, Creighton University School of Medicine.

Primary Study Objective: To examine whether omalizumab given prior to rush immunotherapy (RIT) followed by 12 weeks of dual omalizumab and IT is more effective than RIT followed by IT alone in preventing the symptoms of ragweed-induced SAR.
Secondary Study Objective: To examine whether omalizumab given prior to RIT followed by 12 weeks of dual omalizumab and IT is safe and more effective than omalizumab alone or placebo in preventing the symptoms of ragweed-induced SAR; to assess the immunologic mechanisms associated with the therapies; and to assess whether clinical tolerance has been achieved after discontinuation of the therapies.



Inclusion Exclusion Criteria Block

Inclusion Exclusion Criteria	
Category	Criterion
Inclusion	A positive skin test by prick method to ragweed pollen at Visit -01. A positive skin prick test will be defined as a ragweed pollen-induced wheal >3 mm larger in diameter than diluent control (measurements will be made 15-20 minutes after application).
Inclusion	History of seasonal allergic rhinitis for at least 2 years with symptoms during the ragweed pollen season requiring pharmacotherapy.
Inclusion	Female participants of child bearing age must have a negative urine pregnancy test at Visit -01 and a negative urine pregnancy test at subsequent visits. In addition, female participants must be using a medically acceptable form of birth control.
Inclusion	Male or female 18 to 50 years of age.
Inclusion	Must be capable of faithfully completing the diary and of attending regularly scheduled study visits.
Inclusion	Participants must have a baseline serum IgE level > 10 and < 700 IU/mL.
Inclusion	Participants must meet pretrial eligibility requirements for trial enrollment (acceptable medical history, physical examination results, normal electrocardiogram and acceptable laboratory test results).
Inclusion	Willing to avoid prohibited medications for the periods indicated in the protocol.
Inclusion	Must intend to remain in the ragweed pollen area during the entire ragweed season.
Inclusion	Able to comprehend and grant a witnessed, written informed consent prior to any study procedures.
Exclusion	Documented evidence of acute or significant chronic sinusitis, as determined by the Investigator.
Exclusion	Asthma (either history of, abnormal spirometry, [FEV1 <80% predicted] or use of asthma medications).
Exclusion	Chronic or intermittent use of inhaled, oral, intra-muscular, or intra-venous corticosteroids; or chronic or intermittent use of topical corticosteroids within 4 weeks of Visit -01.
Exclusion	Chronic use of medications (e.g., tricyclic antidepressants) that would affect assessment of the effectiveness of the study medication.
Exclusion	Rhinitis medicamentosa.
Exclusion	History or presence of significant renal, hepatic, neurologic, cardiovascular, hematologic, metabolic, cerebrovascular, respiratory, gastrointestinal or other significant medical condition including, autoimmune or collagen vascular disorders, aside from organ-specific autoimmune disease limited to the thyroid that in the Investigator's opinion could interfere with the study or require medical treatment that would interfere with the study.
Exclusion	History of cancer other than basal cell carcinoma of the skin.

Study Demographics

Study Demographics and Assessments Blocks

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Demographic Statistic	ARM 1	ARM 2	ARM 3	ARM 4
Min Age	19 years	18 years	18 years	18 years
Mean Age	35 years	32 years	32 years	34 years
Max Age	50 years	49 years	49 years	49 years
Gender - Male (Count)	22	12	20	18
Gender - Female (Count)	17	28	20	22
Gender - Male (Percent of Arm)	56.41 %	30.00 %	50.00 %	45.00 %

ARM 1 - Immunotherapy with anti-IgE
 ARM 2 - Placebo Immunotherapy with anti-IgE
 ARM 3 - Immunotherapy with placebo anti-IgE
 ARM 4 - Placebo Immunotherapy with placebo anti-IgE

Assessments

Assessments Summary

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Assessment Name Reported	Total	ARM 1	ARM 2	ARM 3	ARM 4
Participant Diary Card Record	Assessment Components	66,948	73,045	65,604	64,078
Participant Diary Card Record	Subjects	36	38	37	38
Vital Signs	Assessment Components	6,841	7,081	7,067	7,108
Vital Signs	Subjects	39	40	40	40

ARM 1 - Immunotherapy with anti-IgE
 ARM 2 - Placebo Immunotherapy with anti-IgE
 ARM 3 - Immunotherapy with placebo anti-IgE
 ARM 4 - Placebo Immunotherapy with placebo anti-IgE

Assessment Component List

Export - exports the current table to Excel or PDF
 All Study Assessments - opens a new window with all assessment values for this study
 Component links - opens a new window with all assessment values for that component

Information on the study demographics as well as the study assessments are indicated on this page. These can be exported for further analysis

Page 1 of 1 | Export | All Study Assessments | Displaying 1 - 16 of 16

Assessment	Assessment Component
Participant Diary Card Record	Itchy Nose Throat Severity Score
Participant Diary Card Record	Itchy Watery Eyes Severity Score
Participant Diary Card Record	Nasal Congestion Severity Score
Participant Diary Card Record	Number of Rescue Medication Taken
Participant Diary Card Record	Runny Nose Score
Participant Diary Card Record	Sneezing Severity Score

Concomitant Medications Block

SDY1
SDY10
Collapse All: Expand All:

Study Summary +

Demographics +

Assessments +

Concomitant Medications -

Concomitant Medications Summary

Page 1 of 1 Export Displaying 1 - 2 of 2

Totals By	ARM 1	ARM 2	ARM 3	ARM 4
Concomitant Medications	119	157	116	114
Subjects	38	40	40	40

ARM 1 = Immunotherapy with anti-IgE
 ARM 2 = Placebo Immunotherapy with anti-IgE
 ARM 3 = Immunotherapy with placebo anti-IgE
 ARM 4 = Placebo Immunotherapy with placebo anti-IgE

Concomitant Medications Detail

Adverse Events Block

Adverse Events

Adverse Events Summary

Page 1 of 1 | Export | Displaying 1 - 8 of 8

Totals By	ARM 1	ARM 2	ARM 3	ARM 4
Death Adverse Events	0	0	0	0
Life Threatening Adverse Events	0	1	1	0
Mild Adverse Events	315	311	296	268
Moderate Adverse Events	122	127	150	119
Severe Adverse Events	29	40	46	28
Subjects	39	40	40	40

ARM 1 - Immunotherapy with anti-IgE
 ARM 2 - Placebo Immunotherapy with anti-IgE
 ARM 3 - Immunotherapy with placebo anti-IgE
 ARM 4 - Placebo Immunotherapy with placebo anti-IgE

Adverse Event Detail

Export - exports the current table to Excel or PDF
 All Study Adverse Events - opens a new window with all adverse event values for this study
 Name Reported links - opens a new window with all adverse event values for that reported name

Page 1 of 48 | Export | All Study Adverse Events | Displaying 1 - 25 of 1193

Name Reported	Severity	Total Count	ARM 1	ARM 2	ARM 3	ARM 4
CARCINOMA OF LEFT BREAST	Life Threatening	1		1		
ANAPHYLAXIS	Life Threatening	1			1	
UTERINE FIBROIDS	Severe	1	1			
GASTROENTERITIS	Severe	1				1
URTICARIA	Severe	6	2		3	1
SOB	Severe	1				1

ARM 1 - Immunotherapy with anti-IgE
 ARM 2 - Placebo Immunotherapy with anti-IgE
 ARM 3 - Immunotherapy with placebo anti-IgE
 ARM 4 - Placebo Immunotherapy with placebo anti-IgE

Clinical Lab Tests Block

Clinical Lab Tests ≡

Clinical Lab Test Panels

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Lab Test Panel Name	Totals By	ARM 1	ARM 2	ARM 3	ARM 4
Hematology	Lab Tests	4,257	4,389	4,432	4,444
Hematology	Biological Samples	328	339	341	344
Hematology	Subjects	39	40	40	40
Total IgE	Biological Samples	40	40	40	40
Total IgE	Subjects	39	40	40	40
Total IgE	Lab Tests	40	40	39	41

ARM 1 - Immunotherapy with anti-IgE
 ARM 2 - Placebo Immunotherapy with anti-IgE
 ARM 3 - Immunotherapy with placebo anti-IgE
 ARM 4 - Placebo Immunotherapy with placebo anti-IgE

Clinical Lab Tests

Export - exports the current table to Excel or PDF
 All Study Lab Tests - opens a new window with all lab test values for this study
 Lab Test Links - opens a new window with all lab test values for that lab test

Page 1 of 2 Export All Study Lab Tests Displaying 1 - 25 of 27

Lab Test Panel	Lab Test
Hematology	BANDS
Hematology	BASOPHILS
Hematology	EOSINOPHILS
Hematology	HEMATOCRIT
Hematology	HEMOGLOBIN
Hematology	LARGE UNCLASSIFIED CELLS

Mechanistic Assay and Documentation Blocks

Concomitant Medications Detail

Adverse Events ▢

Clinical Lab Tests ▢

Mechanistic Assays ▢

Mechanistic Assays

Page 1 of 1 View Details Export Displaying 1 - 2 of 2

<input type="checkbox"/>	Exp Accession	User Def Id	Exp Title	Exp Type	Exp Meas Tech	Num of Exp Samples
<input type="checkbox"/>	EXP3727	RPCIFLOW_ITN019AD	RPCIFLOW_ITN019AD	Cellular_Quantification	FCM	11708
<input type="checkbox"/>	EXP3903	ELISA/DACI_ITN019AD	Antigen Specific Antibodies	Cytokine_Quantification	ELISA	4376

Documentation ▢

Protocol Name	Protocol File
Apoptosis	Apop_panel_definition.xls
Clinical	Casale ITN019AD Protocol v8.0.pdf
ELISA_protocol	PlaceholderProtocol.doc
Flow Surface	Flow_panel_definition.xls