

**The ITMIG INTERNATIONAL PROSPECTIVE DATABASE
DATA FIELDS BY CASE REPORT FORM**

Data Collected by Patient and Episode (field ID code in blue)

June 6, 2017

ENROLLMENT	
Patient ID ENR001	Generated by ITMIG
Prospective ENR002	Yes if prospective, no if retrospective. Both prospective and retrospective patients are entered into this database to support research projects.
Gender ENR003	Male, Female, Not Available
Date of Birth ENR004	ITMIG uses date format YYYY-MM-DD
If Date of Birth not Available Age at Clinical Diagnosis ENR005	Enter value in years
Race ENR006	African-American, Native American/Alaskan Native, Asian/Pacific Islander, Caucasian, Eskimo and Aleut, Hispanic, Mexican American, Middle Eastern, Other If Other, enter Race
Country of Birth ENR007	Choose from list
City of Birth ENR008	Enter text
City of Birth ENR009	Enter text
Comments ENR010	Enter text
INITIAL PRESENTATION	
Clinical Date of Diagnosis PRE001	
Pathologic Date of Diagnosis PRE002	
Diagnosis of Paraneoplastic/Autoimmune Syndrome PRE003	None, Myasthenia Gravis, Red Cell Aplasia, Hypogammaglobulinemia, Cushing' syndrome, Multiple Endocrine Neoplasia (MEN) 1 or 2, Unknown, Other If Other enter Diagnosis

Myasthenia MGFA Classification PRE004	None, I, II, III, IV, V
Duration of Myasthenia (months) PRE005	Enter value
Previous Neoplasm (select all that apply) PRE006	None, Breast, Lung, Colon, Prostate, Skin, Lymphoma, MEN-related Tumor, Other If Other enter Previous Neoplasm
If Previous Neoplasm, history of chemotherapy for previous neoplasms PRE007	For each previous neoplasm, enter Yes or No for history of chemotherapy
If Chemotherapy for Previous Neoplasm, chemotherapy agents PRE008	For each previous neoplasm with history of chemotherapy, enter chemotherapy agents
Zubrod Score PRE009	0 - Asymptomatic, 1 – Symptomatic but completely ambulatory. (Able to Work), 2 – In bed < 50% of the day (Unable to work but able to live at home with some assistance), 3 - In bed > 50% of the day (Unable to care for self), 4 - Bedbound
Comments PRE010	Enter text
IMAGING By Episode, data for any number of recurrences is collected Multiple entries for any or all imaging types allowed for each episode	
SCAN ID IMG001	Generated by ITMIG
Purpose IMG002	Initial Assessment, Treatment Assessment
If Treatment Assessment Select Treatment Type IMG003	Chemotherapy, Radiation
For Treatment Type Selection (Chemotherapy or Radiation) Select treatment start date IMG004	Select which treatment by date of initiation (there can be multiple treatments)
CT	

Date of CT Imaging IMG005	
Intravenous Contrast IMG006	No, Yes
Longest diameter IMG007	Enter value in cm
Second dimension IMG008	Enter value in cm
Third dimension IMG009	Enter value in cm
Contour IMG010	Smooth, Lobulated
Internal Density IMG011	Homogeneous, Heterogeneous, Cystic
Calcification IMG012	No, Yes, Unknown
Infiltration of Mediastinal Fat IMG013	No, Yes
Abutment of >= 50% Of Mediastinal Vessels IMG014	No, Yes
If Yes Vessels (select all that apply) IMG015	None, SVC, Right Innominate Vein, Left Innominate Vein, Innominate Artery, Left carotid artery, Left subclavian vein, Main Pulmonary artery, Aorta, Other If Other Enter Vessels
Vascular Endoluminal Invasion (select all that apply) IMG016	No, Yes
If Yes Vessels (select all that apply) IMG017	None, SVC, Right Innominate Vein, Left Innominate Vein, Innominate Artery, Left carotid artery, Left subclavian vein, Main Pulmonary artery, Aorta, Other If Other Enter Vessels
Abutment of Adjacent Mediastinal Structures IMG018	No, Yes
If Yes Structures (select all that apply) IMG019	None, Lung, Pericardium, Chest Wall, Phrenic Nerve, Other If Other enter Structures

Invasion of Adjacent Mediastinal Structures IMG020	No, Yes
If Yes Structures (select all that apply) IMG021	None, Lung, Pericardium, Chest Wall, Phrenic Nerve, Other If Other enter Structures
Elevated Hemidiaphragm IMG022	No, Yes
Pleural Effusion IMG023	No, Unilateral, Bilateral
Pleural Nodule IMG024	None, Unilateral, Bilateral
If Unilateral Pleural Nodule Unilateral IMG025	1,2-5, >5 Diffuse
If Bilateral Pleural Nodule Bilateral IMG026	1,2-5, >5 Diffuse
Mediastinal Lymph Node Enlargement (>1cm in short axis diameter) IMG027	No, Yes
If Yes Location IMG028	Enter text
Pulmonary Nodule / Metastasis IMG029	No, Yes
Suspected Extrathoracic Metastasis IMG030	No, Yes
If Yes Location of the Extrathoracic Metastasis IMG031	Enter text
Comment Include radiologist impression from report. IMG032	Enter text
PET	

Date of PET Imaging IMG033	
Maximum SUVBW of Primary Lesion IMG034	Enter value
Radionucleotide uptake in metastasis IMG035	No, Yes
If Yes, Organ where Radionucleotide showed metastatic uptake IMG036	Enter text
Comment Include radiologist impression from report. IMG037	Enter text
MRI	
Date of MRI Imaging IMG038	
Intravenous Contrast IMG039	No, Yes
Longest diameter IMG040	Enter value in cm
Second dimension IMG041	Enter value in cm
Third dimension IMG042	Enter value in cm
Contour IMG043	Smooth, Lobulated
Internal Density IMG044	Homogeneous, Heterogeneous, Cystic
Calcification IMG045	No, Yes, Unknown
Infiltration of Mediastinal Fat IMG046	No, Yes
Abutment of >= 50% Of Mediastinal Vessels IMG047	No, Yes

If Yes Vessels (select all that apply) IMG048	None, SVC, Right Innominate Vein, Left Innominate Vein, Innominate Artery, Left carotid artery, Left subclavian vein, Main Pulmonary artery, Aorta, Other If Other Enter Vessels
Vascular Endoluminal Invasion (select all that apply) IMG049	No, Yes
If Yes Vessels (select all that apply) IMG050	None, SVC, Right Innominate Vein, Left Innominate Vein, Innominate Artery, Left carotid artery, Left subclavian vein, Main Pulmonary artery, Aorta, Other If Other Enter Vessels
Abutment of Adjacent Mediastinal Structures IMG051	No, Yes
If Yes Structures (select all that apply) IMG052	None, Lung, Pericardium, Chest Wall, Phrenic Nerve, Other If Other enter Structures
Invasion Of Adjacent Mediastinal Structures IMG053	No, Yes
If Yes Structures (select all that apply) IMG054	None, Lung, Pericardium, Chest Wall, Phrenic Nerve, Other If Other enter Structures
Elevated Hemidiaphragm IMG055	No, Yes
Pleural Effusion IMG056	No, Unilateral, Bilateral
Pleural Nodule IMG057	None, Unilateral, Bilateral
If Unilateral Pleural Nodule Unilateral IMG058	1,2-5, >5 Diffuse
If Bilateral Pleural Nodule Bilateral IMG059	1,2-5, >5 Diffuse
Mediastinal Lymph Node Enlargement (>1cm in short axis diameter)	No, Yes

IMG060	
If Yes Location IMG061	Enter text
Pulmonary Nodule / Metastasis IMG062	No, Yes
Suspected Extrathoracic Metastasis IMG063	No, Yes
If Yes Location of the Extrathoracic Metastasis IMG064	Enter text
Comment Include radiologist impression from report. IMG065	Enter text
OCTREOSCAN	
Date of Octreoscan Imaging IMG066	
Octreoscan Result in Primary Tumor IMG067	Positive, Negative
Radionuclide uptake in metastasis IMG068	No, Yes
If Yes, Organ where Radionuclide showed metastatic uptake IMG069	Enter text
Comments Include radiologist impression from report. Specify if radionuclide uptake was seen in metastasis IMG070	Enter text
SURGERY By Episode, data for any number of recurrences is collected	
Date of Surgery	

SUR001	
Approach SUR002	Sternotomy, Thoracotomy, Hemi-clamshell, Clamshell, VATS, VATS-robotoc, Transcervical, Cervical with Sternal Split, Sternotomy + Thoracotomy, Chamberlain, Other If Other enter Approach
Clinical Resection Status SUR003	Incomplete, Complete
Tumor Breach during Surgery SUR004	Yes, No
Extent of Thymectomy SUR005	None, Partial, Extended, Total
Resected Structures (select all that apply) SUR006	Lung wedge, Lobectomy/Segmentectomy, Pneumonectomy, Extrapleural Pneumonectomy, Diaphragm, Inferior Vena Cava, Pericardium, Phrenic Nerve, Pleural Implant(s), Superior Vena Cava, None, Other If Other enter Resected Structures
Any Adverse Event (repeat for each Adverse Event) SUR007	No, Yes
If Yes Adverse Event Description SUR008	Enter text Use Common Terminology Criteria for Adverse Events (CTCAE)
Grade SUR009	1,2,3,4,5
Comments Describe any associated procedures such as diaphragm plication SUR010	Enter text
Did patient have adjuvant chemotherapy SUR011	No, Yes
Did patient have adjuvant radiotherapy SUR012	No, Yes
Chemotherapy By Episode, data for any number of recurrences is collected Multiple entries for chemotherapy allowed for each episode	
Intent CHEO001	None, Preoperative, Postoperative, Chemoradiotherapy, Palliative

Date Initiated CHEO002	
Data Completed/Stopped CHEO003	
Regimen (select all that apply) CHEO004	None ADOC Adriamycin, Cisplatin, Vincristin, Cyclophosphamide CAP Cisplatin, Adriamycin, Cyclophosphamide CAMP CAP and Prednisone CAPGEM Capecitabine, Gemcitabine Carbo-Px Carboplatin Paclitaxel CEE Cisplatin, Epirubicin, Etoposide Cisplatin alone CODE Cisplatin, Vincristin, Adriamycin, Etoposide Ifosfamide alone Irinotecan alone PE Cisplatin, Etoposide Pemetrexed alone VIP Etoposide, Ifosfamide, Cisplatin Paclitaxel 5FU +/- Leucovorin Other If Other, enter Regimen
Number of Cycles CHEO005	Enter value
Dose Intensity CHEO006	>70% <70% planned dose intensity
Corticosteroids CHEO007	No, Yes
if Yes Corticosteroids Duration CHEO008	Enter value in months
Comments If this regimen is stopped, enter reason for stopping (toxicity, progression): CHEO009	Enter text
Any Adverse Event (repeat for each Adverse Event) CHEO010	No, Yes
If Yes Adverse Event Description CHEO011	Enter text Use Common Terminology Criteria for Adverse Events (CTCAE)
Grade	1,2,3,4,5

CHEO012	
Best Treatment Response (RECIST Criteria) Not available when Intent is None or Postoperative CHEO013	Complete Response (CR), Not Applicable: No Target (NA), Partial Response (PR), Progressive Disease (PD), Stable Disease (SD)
Date of Response Assessment Not available when Intent is None or Postoperative CHEO014	
Radiotherapy By Episode, data for any number of recurrences is collected Multiple entries for radiotherapy allowed for each episode	
Intent RADO001	None, Preoperative, Primary Definitive, Postoperative, Palliative
Date Initiated RADO002	
Date Completed RADO003	
Fields (select all that apply) RADO004	None, Tumor with Margin, Tumor Bed with Margin, Elective Mediastinum Beyond Initially Involved Area, Involved Lymph Nodes, Elective Lymph Nodes, Sites of Pleural Metastases, Hemithorax, Other If Other enter Field
Technique RADO005	2D planning, 3D conformal, IMRT, Proton Therapy, Unknown, Other If Other enter Technique
Total Dose RADO006	Enter value
Fraction Size RADO007	Enter value
Boost RADO008	Concurrent, None, Sequence unknown, Sequential
Boost Dose RADO009	Enter value
Fraction Size RADO010	Enter value
Concurrent Chemotherapy RADO011	No, Yes
Any Adverse Event (repeat for each Adverse	No, Yes

Event) RADO012	
If Yes, Adverse Event Description RADO013	Enter text Use Common Terminology Criteria for Adverse Events (CTCAE)
Grade RADO014	1,2,3,4,5
Best Treatment Response (RECIST Criteria) Not available when Intent is None or Postoperative RADO015	Complete Response (CR), Not Applicable (NA), Partial Response (PR), Progressive Disease (PD), Stable Disease (SD)
Date of Response Assessment Not available when Intent is None or Postoperative RADO016	
PATHOLOGY By Episode, data for any number of recurrences is collected Multiple entries for biopsy allowed for each episode	
BIOPSY	
Date of Pathology Assessment BIO001	
Sample BIO002	FNA Biopsy, Core Biopsy, Surgical Biopsy
Diagnosis BIO003	Thymoma, Thymic Carcinoma, Neuroendocrine Tumors, Thymic Malignancy NOS, Benign, Other If Other enter Diagnosis
If Thymoma WHO Classification (select all that apply) BIO004	A, AB, B1, B2, B3, Not otherwise specified
If Thymic Carcinoma Histology (select all that apply) BIO005	Squamous cell, Lymphoepithelioma-like, Sarcomatoid, Mucoepidermoid, Adenocarcinoma, Clear cell, Not otherwise specified, Basaloid, Other If Other enter Histology
If Neuroendocrine Tumors (NETT) Histology BIO006	Well-differentiated/Typical carcinoid, Moderately-differentiated/Atypical carcinoid, Large Cell Neuroendocrine Carcinoma, Small Cell Carcinoma, Not otherwise specified

Comments BIO007	Enter text
RESECTION	
Date of Pathology Assessment RES001	
Frozen Section Diagnosis RES002	Thymoma, Thymic Carcinoma, Neuroendocrine Thymic Tumor (NETT), Thymic Malignancy NOS, Other Malignancy, Benign, Other If Other enter Diagnosis
Final Pathologic Diagnosis RES003	Thymoma, Thymic Carcinoma, Neuroendocrine Thymic Tumor (NETT), Thymic Malignancy NOS, Other Malignancy, Benign, Other If Other enter Diagnosis
If Thymoma WHO Classification (select all that apply) RES004	A, AB, B1, B2, B3, Not otherwise specified
If Thymic Carcinoma Histology (select all that apply) RES005	Squamous cell, Lymphoepithelioma-like Sarcomatoid, Mucoepidermoid, Adenocarcinoma, Clear cell, Not otherwise specified, Basaloid, Other If Other enter Histology
If Neuroendocrine Thymic Tumor (NETT) Histology RES006	Well-differentiated/Typical carcinoid, Moderately-differentiated/Atypical carcinoid, Large Cell Neuroendocrine Carcinoma, Small Cell Carcinoma, Not otherwise specified
Method for Tumor Dimension data entry RES007	Width, height, length of tumor Largest to smallest dimension of tumor
Tumor Size 3 dimensions	
Width or longest dimension RES008	Enter value in cm
Height or second longest dimension RES009	Enter value in cm
Length or smallest dimension RES010	Enter value in cm
Number of sections examined RES011	Enter value
Transcapsular invasion	No, No capsule, Yes, Yes 3mm or more, Yes < 3mm

RES012	
Overall Margin Status RES013	Negative, Positive
Number of margin sections examined RES014	
Adjacent Organ Involvement (select all that apply) RES015	None, Not evaluated, Mediastinal Fat/Thymus, Mediastinal Pleura, Pericardium, Visceral Pleura, Lung, Bone, Phrenic Nerve, Great Vessels, Other If Other enter Adjacent Organ Involvement
If Mediastinal Fat/Thymus Direct Spread RES016	Yes, No, Not determinable
If Mediastinal Fat/Thymus Separate Nodule RES017	Yes, No, Not determinable
If Mediastinal Pleura (through) Direct Spread RES018	Yes, No, Not determinable
If Mediastinal Pleura Separate Nodule RES019	Yes, No, Not determinable
If Pericardium (into or through) Direct Spread RES020	Yes, No, Not determinable
If Pericardium Separate Nodule RES021	Yes, No, Not determinable
If Visceral Pleura Direct Spread RES022	Yes, No, Not determinable
If Visceral Pleura Separate Nodule RES023	Yes, No, Not determinable
If Lung Direct Spread RES024	Yes, No, Not determinable
If Lung Separate Nodule RES025	Yes, No, Not determinable

If Bone Direct Spread RES026	Yes, No, Not determinable
If Bone Separate Nodule RES027	Yes, No, Not determinable
If Phrenic Nerve Direct Spread RES028	Yes, No, Not determinable
If Phrenic Nerve Separate Nodule RES029	Yes, No, Not determinable
If Great Vessels Direct Spread RES030	Yes, No, Not determinable
If Great Vessels Separate Nodule RES031	Yes, No, Not determinable
If Other Direct Spread RES032	Yes, No, Not determinable
If Other Separate Nodule RES033	Yes, No, Not determinable
Number of Lymph Nodes evaluated RES034	Enter value
Number of Lymph positive RES035	Enter value
Multifocal Tumor RES036	Yes, No
If Yes, Number of Foci of Tumor RES037	Enter value
Cystic Tumor RES038	Yes, No
If Yes, Was cyst opened during surgery RES039	Yes, No
Was Capsule Visible Histologically	Yes, No

RES040	
Comments: Also include the following: 1. Record Treatment effect in 10% increments. 2. Note if surface of the tumor was exposed during resection. RES041	Enter text
Tumor Bank Information about tumor tissue specimens, normal tissue specimens, and blood samples	
Tumor Tissue	
Thymus Formalin-fixed paraffin-embedded (FFPE) blocks TUB001	Yes, No If Yes Size/Volume (cm3) Repeat for any number of specimens
Thymus Frozen TUB002	Yes, No If Yes Size/Volume (cm3) Repeat for any number of specimens
Pleura Formalin-fixed paraffin-embedded (FFPE) blocks TUB003	Yes, No If Yes Size/Volume (cm3) Repeat for any number of specimens
Pleura Frozen TUB004	Yes, No If Yes Size/Volume (cm3) Repeat for any number of specimens
Lung Formalin-fixed paraffin-embedded (FFPE) blocks TUB005	Yes, No If Yes Size/Volume (cm3) Repeat for any number of specimens
Lung Frozen TUB006	Yes, No If Yes Size/Volume (cm3) Repeat for any number of specimens
Other Formalin-fixed paraffin-embedded (FFPE) blocks TUB007	Yes, No If Yes Text specifying site Size/Volume (cm3) Repeat for any number of specimens
Other Frozen	Yes, No If Yes

TUB008	Text specifying site Size/Volume (cm3) Repeat for any number of specimens
Normal Tissue	
Normal Thymus Formalin-fixed paraffin- embedded (FFPE) blocks TUB009	Yes, No If Yes Size/Volume (cm3) Repeat for any number of specimens
Normal Thymus Frozen TUB010	Yes, No If Yes Size/Volume (cm3) Repeat for any number of specimens
Other Formalin-fixed paraffin- embedded (FFPE) blocks TUB011	Yes, No If Yes Text specifying site Size/Volume (cm3) Repeat for any number of specimens number of specimens
Other Frozen TUB012	Yes, No If Yes Text specifying site Size/Volume (cm3) Repeat for any number of specimens number of specimens
Blood samples	
Whole blood Frozen TUB013	Yes, No If Yes # vials
Peripheral blood mononuclear cell (PBMC) TUB014	Yes, No If Yes # vials
STAGING By Episode, data for any number of recurrences is collected	
Clinical Masaoka-Koga Stage (Pre-treatment) STA001	I, II, IIA, IIB, III, IVA, IVB, No radiographic evidence of tumor
Pathologic Masaoka-Koga Stage (Post-resection) STA002	I, II, IIA, IIB, III, IVA, IVB, No pathology
Final Pathologic Resection Status STA003	R0, R1, R2, RX

(TNM) Primary Tumor STA004	TX, T1a, T1b, T2, T3, T4
(TNM) Regional Lymph Nodes STA005	NX, N0, N1, N2, N3
(TNM) Distant Metastasis STA006	MX, M0, M1a, M1b
If R1 or R2 Location of the Residual STA007	Mediastinum, Great Vessels, Pleura, Pericardium, Phrenic Nerve, N/A, Other If Other, enter Location
Enter Sites of Metastatic Disease (organs and/or lymph nodes) STA008	Enter text
Was Metastatic Biopsy Proven STA009	Yes, No
Comments STA0010	Enter text
FOLLOW-UP By Episode or by follow-up schedule based on stage and treatment completion date	
Episode FUP001	Generated by ITMIG, first episode is "initial", follow-up episodes identify recurrence number and date.
Vital Status FUP002	Alive no evidence of disease, Alive persistent disease, Alive new recurrence of disease, Dead
If Dead Date of Death or Last known alive FUP003	
If Dead Cause of Death FUP004	Unknown, Thymoma or complications associated with thymoma, Treatment complications, Myasthenia Gravis or Myasthenia Gravis-related death, Other If Other enter Cause of Death
If Alive No Evidence of Disease Date Last known alive FUP005	
If Alive Persistent Disease Date Last known alive FUP006	
If Alive Recurrence	

Date Last known alive FUP007	
Recurrence Episode number FUP008	(automatically set by system)
Date of First Detection Scan FUP009	
Modality of Recurrence Diagnosis (select all that apply) FUP010	CT, PET, MRI, Octreoscan
Is there a Histologic Confirmation of the recurrence FUP011	No, Yes
If Yes Date of pathologic confirmation of recurrence FUP012	
Location of recurrence (select all that apply) FUP013	Distant recurrence - extrathoracic or intrapulmonary, Local recurrence - anterior mediastinum, Regional recurrence - intrathoracic
Describe the site of the recurrence (ex. Pleura, lung, bed of the thymus, etc) FUP014	Enter text
Recurrence related to radiation treatment FUP015	In-Field, Marginal Recurrence, Out-Of-Field, No-Radiation, Field Unknown, Other If other enter Recurrence relationship
Is there a second diagnosed malignancy FUP016	No, Yes
If Yes, Second Malignancy Description FUP017	Enter text
Chemotherapy for second diagnosed malignancy FUP018	Malignancy and Yes, No
Chemotherapy agents for second diagnosed malignancy	Malignancy, Chemotherapy agents

FUP019	
Status of Myasthenia Gravis FUP020	Not Available, Remission, Improved, Unchanged, Worse, Died of Myasthenia Gravis, Other If Other enter Status
PATHOLOGY REPORTS By Episode, any number of PDF, WORD or TXT documents can be uploaded	
Filename	
File Description	
File Size	
File Upload Date	
IMAGES (PATHOLOGY, RADIOLOGY) By Episode, any number of JPG, GIF, BMP or other image formats can be uploaded	
Filename	
File Description	
Image Thumbnail	
File Size	
File Upload Date	
DICOMS By Episode, any number Dicom files can be uploaded	
Filename	
File Description	
Dicom Thumbnail	
File Size	
File Upload Date	
OTHER DATA FILES By Episode, any number of files in any format, e.g., XLS, XLSX	
Filename	
File Description	
File Size	
File Upload Date	
SUBMITTER INFORMATION For each CRF	

Submitter Name	
Submitter Hospital	
Submission Date	