Transthyretin Amyloidosis Outcomes Survey (THAOS)  
Publication Manual

Registry Oversight Body:  
THAOS Scientific Board

Registry Sponsor:  
Pfizer Inc  
235 E 42\textsuperscript{nd} Street, 10017 New York, NY

Protocol Version:  
Version 1.1

Protocol Release Date:  
02 May 2013

Replaces Previous Version (date):  
1.0

Administrative Change:  
- Sponsor name update from FoldRx to Pfizer Inc.  
- Addendum 3 updated with up to date publications

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**Glossary of Terms:**

1. **Board** (THAOS Scientific Board) – an international group of amyloid experts who provide scientific oversight, analysis and interpretation of data originating from THAOS
2. **P&P Committee** (Publications and Presentation Committee) – a subset of the THAOS Scientific Board charged with reviewing and approving THAOS publications
3. **P&P Rep** (Publications and Presentations Committee Representative) – a member of the P&P Committee who provides guidance on the specific data analysis and publication draft preparation for a given proposal under review, to ensure that the proposal adheres to the objectives of the registry and the guidelines set forth in this document
4. **PPI** (Publication Proposal Index) – an up-to-date listing of all submitted and approved THAOS publication proposals
5. **TPPF** (THAOS Publication Proposal Form) – an electronic document used to submit a publication proposal for review and approval by the P&P Committee
6. **THAOS Publication Strategy** – the stated goals of THAOS publications for the upcoming year, including prioritization of approved THAOS data analyses and the selection of the timing and venue for dissemination of these analyses
7. **Writing Group Chair** – the investigator responsible for submitting a publication proposal and coordinates efforts of the writing group in preparing the publication; key contact person with the P&P Committee and publication venue reviewers
8. **Writing Group** – subgroup of THAOS investigators charged with conducting the data analyses, interpretation and publication preparation for an approved publication proposal

**Introduction:**

The principal aim of THAOS is to provide an improved understanding and a more complete characterization of the natural history of transthyretin (TTR) amyloidosis (ATTR) by studying a large and heterogeneous patient population in a longitudinal manner. Data collected by the registry may be potentially useful for the development of new treatment guidelines and recommendations to inform and educate clinicians on more effective management of this disease. The ultimate goal is to improve the care and treatment of ATTR patients.

It is anticipated that over one thousand patients will be enrolled across greater than 50 survey sites. The THAOS registry is web-based facilitating the secure, remote submission of clinical data from all participant sites. Patient data collected by THAOS will be analyzed periodically by the THAOS Scientific Board, subsequently referred to as the “Board,” and data from these analyses will be disseminated to the medical community via a series of scientific publications and presentations. The Board, is an international group of amyloid experts who provide scientific oversight, analysis and interpretation of data originating from THAOS on an ongoing basis throughout the 10-year active duration of the registry. The Board may also utilize the registry data to develop treatment recommendations and practice guidelines for patients with transthyretin amyloidosis. The Board will establish the scientific policies and make decisions related to the use of the registry data, including prioritization of data analyses within the approved annual budget and biostatistical resources provided by the THAOS sponsor, Pfizer Inc.
The purpose of this document is to define a process for management of the analyses of data generated by the registry. A clearly defined publication process will facilitate a collaborative effort between the Board and individual THAOS investigators to determine the nature of data analyses to be performed, the timing and prioritization of these analyses, and suggested publication venues. All proposed publications and presentations generated and approved via this process will be consistent with the defined goals and objectives of the registry and will take into account the input and suggestions of each investigator participating in the registry.

Authorship and publication guidelines established herein will be reviewed and approved by the Board in accordance with the standards of the International Committee of Medical Journal Editors (ICMJE).

**Objectives of the THAOS Publication Manual:**

- To document a process for developing, disseminating, and updating an annual THAOS publication strategy
- To document procedures for data analysis proposal submission, review and approval
- To document the process for preparation and review of THAOS publications
- To document authorship standards and guidelines for THAOS publications

**Publication Oversight and Review**

There are two oversight bodies that are responsible for ensuring timely and on-going publication of THAOS data: The THAOS Scientific Board and the THAOS Publication and Presentations Committee (P&P Committee).

The strategic duties of the Board are:

- To determine the THAOS Publication Strategy and to communicate the initial as well as updated (based on ongoing proposals) strategy to all participating THAOS sites at regular intervals during the registry
- To prioritize data analyses within the approved annual budget and biostatistical resources provided by Pfizer Inc.
- To ensure and expedite the timely publication and presentation to the scientific community of all pertinent THAOS data

The P&P Committee will be responsible for the operational oversight of the THAOS publication process. In the initial stages of THAOS, membership in this committee will be limited to members of the THAOS Scientific Board. As the registry database expands and the volume of proposals and opportunities for proposals grows, the P&P Committee will evolve to comprise a subset of members of the THAOS Scientific Board as well as other THAOS investigators. In addition, on an ad hoc basis, other reviewers who possess specific expertise uniquely applicable to the given subject matter of a particular analysis in the documents under review may be asked to participate. The responsibilities of the P&P Committee include the following:
• To assign a P&P Committee Representative (P&P Rep) to any submitted proposal
• To review and approve publication proposals
• To provide ongoing support throughout the publication submission and review process until acceptance for publication is achieved

As described above, the Board and the P&P Committee are responsible for oversight of data analysis and publication of the pooled THAOS data, and any subset of the pooled data that involves two or more sites. An individual THAOS site is free to publish clinical data from that site without approval from the P&P Committee. In addition, THAOS sites within a single country may publish country specific data from THAOS, if all THAOS sites within that country agree to participate. A courtesy notification of the planned analysis and publication would allow the Board to review the THAOS publication strategy to determine if modifications are required.

Publication Proposal Development Process:

THAOS publication proposals will be generated primarily by the Board and by the individual THAOS participating sites.

1. The Board will identify specific concepts for analysis and publication based on their review of periodic reports generated by the THAOS statistician. These reports, their general content, and frequency of issue are as follows:

   • Enrollment Reports: Enrollment reports will be generated every 90 days, beginning when a minimum of 50 patients have been enrolled in THAOS. Examples of the types of variables which will be analyzed in this report include: # active sites, # patients enrolled with baseline data, # patients enrolled with follow- up data, # and types of TTR mutations, geographic distribution of TTR mutations, mutations per site, etc.

   • Baseline Reports: Baseline reports will be generated every 180 days and will capture baseline clinical variables on all enrolled patients in a cumulative fashion, following the enrollment of the first 50 patients. All clinical variables entered into the database will be captured in these reports.

   • Follow- up Reports: Follow-up reports will present change from baseline analyses for all available clinical variables. These reports will begin at the first six-month time point following the attainment of 50 patients for whom follow up data is available.

2. Each THAOS investigator is encouraged to generate data analysis/publication proposals based upon their knowledge of the disease, observations from individual site patient data, or new developments in ATTR research reported in the literature. Each investigator has full access to their individual site data, and has full access to analyze these data at any time. The publication proposals generated by the site for consideration by the P&P Committee will be for any cross-site data analysis (e.g. full THAOS dataset or a subset of sites).
3. In addition, an external collaborator may submit a data analysis proposal via a Board Member or a participating THAOS investigator.

All proposals, whether generated by the Board or by a THAOS investigator, will be submitted using the THAOS Publications Proposal Form (TPPF) (Addendum 1). The form is to be submitted for review by the P&P Committee via the THAOS website (www.THAOS.net). This form and submission process can be accessed via the Investigator Portal on the THAOS website.

For coordination and tracking purposes, an up-to-date listing, the Publication Proposal Index (PPI), of all submitted and approved proposals along with their associated review, approval, and start dates has been created. This PPI will also be available on the THAOS website.

**THAOS Publication Strategy:**

The THAOS Board, as one of its primary objectives, will promote and facilitate the dissemination of THAOS data via an ongoing series of scientific publications throughout the duration of the registry. In order ensure the coordinated planning and execution of periodic publications, the Board will prepare the **THAOS Publication Strategy**, which will describe the goals of THAOS publications for the upcoming year, with prioritization of data analyses to be conducted and timing and venue for dissemination.

The Board will communicate the THAOS Publication Strategy to all THAOS investigators via the THAOS website. The primary goal of this Strategy is to communicate analysis priorities, to stimulate the generation of additional proposals from the THAOS investigators, and to inform the THAOS investigator community on the progress of the registry towards meeting its overall objectives. The Publication Strategy will evolve over time, based on the proposals received and approved.

**Publication Proposal Submission and Review Process:**

Steps in the publication proposal submission process are as follows: (see also Figure 1)

1. **Proposal Topic Identification:**
   Selection of a topic of interest for potential publication should be guided initially by the availability within the registry of a sufficient quantity of relevant data necessary to complete the proposed analysis. The THAOS website (www.THAOS.net) will include a summary of overall enrollment status as well as an overall summary of data available for analysis. A list of the general categories of clinical data variables available for query in THAOS is provided as an attachment to this document (Addendum #2) and is available for review on the Investigator Portal of the THAOS website.

2. **Proposal Draft Preparation:**
   A written proposal outlining the key elements of and the rationale for the intended analysis should be prepared using the THAOS Publication Proposal Form (TPPF).
Section 1 of the TPPF solicits general information such as the topic of the analysis, a working title, a listing of the proposed writing group members with their contact information, the type of publication (manuscript, abstract, poster, etc.), and list of target publication venues (journals, society meetings, etc).

Section 2, the narrative portion of the proposal, will discuss the rationale and background information justifying supporting the analysis as well as a brief data analysis plan. Section 2 will consist of no more than three pages of text using 12 pt. Times New Roman font; however, one to two pages should be generally sufficient to provide an appropriate amount of information for review purposes.

3. Submission of a proposal:

Authorship for THAOS publications and presentations is open to all investigators participating in the registry. Any individual or group submitting a proposal for evaluation by the P&P Committee must identify a lead, corresponding author. The lead author, hereafter referred to as the “writing group chair”, will be responsible for completing the publication proposal as well as the various publication drafts generated during the review process. The writing group chair will also select the other members of the “writing group” - the subgroup of THAOS investigators charged with refining the data analyses and supporting the drafting of the publication. Additionally, the writing group chair will be responsible for all communications with the specific journal or organization to which the manuscript, abstract, etc. will be submitted.

The P&P Committee will appoint a P&P Committee Representative (“P&P Rep”) to the writing group for all submitted proposals. The P&P Rep will provide guidance on the specific data analysis and publication draft preparation to ensure that the proposal adheres as closely as possible to the objectives of the registry and the guidelines set forth in this document. The P&P Rep will coordinate all interactions and discussions among the P&P Committee members during the proposal and publication review processes, and will also be a co-author on the final publication. The committee may suggest additional authors to the writing group based on the unique qualifications of those candidates to make valuable contributions to the analysis and/ or publication.

In order to provide appropriate recognition to all sites and investigators who are contributing to THAOS, all proposals that involve composite THAOS data will note the efforts of all co-investigators in an Acknowledgement Statement. A standard Acknowledgement Statement will be provided by the Board and should be included at the end of the text of the publication.

4. P&P Committee Proposal Review:

The primary purpose of this review is to ensure that a clear and accurate preliminary analysis plan is presented. The P&P Committee will review publication proposals on an ongoing basis throughout the duration of the registry. When a new proposal is received by the THAOS Coordinator via the online submission system, a “receipt of proposal” notification will be sent via email to the writing group chair within
7 days. The Coordinator will also assign a P&P Rep and the subgroup of the P&P that will be reviewing the given proposal. The P&P Rep will assume stewardship of the proposal review; including all aspects of the formal review by the P&P Committee (including meeting scheduling, materials dissemination, response collation, etc.). Formal review and approval by the P&P Committee will occur no later than 45 days after receipt of the proposal.

Following approval, a proposal will be assigned a THAOS publication number and entered in the Publication Proposal Index (PPI) on the THAOS website. All future updates and correspondences between the authors and the P&P Committee should reference this number for identification purposes. Any comments generated by the P&P Committee during review will be communicated to the writing group chair by the P&P Rep.

If a proposal is not approved by the P&P Committee, an response explanation will be provided to the chair of the writing group. A proposal that is not approved may be revised, addressing the comments provided by the P&P Committee and re-submitted for consideration. Following resubmission, the process for review will be as outlined above.
Figure 1: THAOS Publication Review Process
(Valid for any data presentation format)

Publication Proposal Submission

P&P Proposal Review

Approved

Central Data Analysis
(Writing group chair, P&P Rep and statistician)

Publication Draft Submission
(Requires all co-author approval)

P&P Publication Review

Revise Draft

Rejected

Revise Analysis

Approved

Rejected: revise or address comments

Rejected: revise or address comments

Board Assists with Alternate Publication Venue

Journal/ Organization Submission

Approved

Publication/ Presentation
Publication Preparation and Review Process:

A primary objective of the P&P Committee is to shepherd approved publication proposals through the review and approval process as efficiently and rapidly as possible. It is anticipated that most proposals will be approved for submission to a scientific journal or organization within 6 months from the date of submission of a publication proposal.

Steps in the approved publication proposal preparation and submission process are as follows: (see also Figure 1 above)

1. **Central Data Analysis:**
   Upon approval of a publication proposal by the P&P Committee, the writing group chair, P&P Rep, and the THAOS statistician begin preparation of a data analysis plan, which is reviewed and approved by all members of the writing group. All pooled data analyses will be conducted centrally by the THAOS Statistician(s).

2. **Publication Preparation:**
   Upon completion of the data analysis, the writing group chair should compose a first publication draft and circulate it to all members of the writing group. Subsequent revisions in response to comments from the writing group will facilitate the completion of a penultimate or “publication-ready” draft. When all members of the writing group have approved the penultimate draft, it is forwarded to the P&P Committee for “publication review”.

3. **Review by P&P Committee:**
   The P&P Committee will review and provide comments (if appropriate) on the penultimate draft to the writing group chair, who will work with the P&P Rep to finalize the publication.

4. **Submission to Publication Venue:**
   The final publication is submitted to a relevant journal or organization for publication by the writing group chair. The writing group chair should forward to the P&P Rep copies of journal correspondence associated with significant revisions along with updated drafts of the publication. When a manuscript, abstract, etc. is accepted, the writing group chair is responsible for providing the P&P Committee with the final draft for inclusion in the THAOS Publications List.

   If a submitted publication is rejected by the primary target publication venue, the writing group chair will work with The P&P Rep to identify alternative journals, meetings, etc for data dissemination, or that no further steps will be taken regarding publication of the data.
Budget Management and Oversight:

The annual budget for publications and presentations will be established by Pfizer Inc. The Board will prioritize use of funds based on adherence and relevance of specific proposals to the annual publication strategy.

THAOS Publication Resources:

THAOS Investigator Website:

The general THAOS Information Website, www.THAOS.net, will contain an interactive website portal, which will be available to the site coordinator and principle investigator at each participating THAOS site. This portal will provide password-protected access to a centralized interactive website on which updated information on THAOS activities and milestones will be available. THAOS Investigator Portal passwords will be issued by the THAOS Administrator at the time of site initiation. Information accessible on the investigator portal includes:

- Notification of site and patient enrollment status (i.e. # sites worldwide and the total number of patients enrolled)
- Annual THAOS Publication Strategy with updates
- Publication Proposal Index (PPI)
  - Master list of all submitted and prioritized approved proposals
  - Start dates and progress updates
  - Abstracts for submitted/reviewed/accepted proposals
- List of Searchable Clinical Variables for proposal creation
- Bibliography of accepted publications and presentations
- Downloadable and online forms and documents associated with THAOS publication submission

Additional materials and resources will be provided as the database grows and the publication strategy progresses. The Board will also consider suggestions for updating and improving the Investigator Portal on an ongoing basis.

THAOS Publication Documents, Forms, Templates, etc.:

- THAOS Publication Proposal Form (TPPF) (Addendum 1)
- THAOS Clinical Data Variables Available for Query (Addendum 2)
- THAOS Publications and Presentations List (Addendum 3)
- THAOS Annual Publication Strategy (Addendum 4)
Addendum 1

THAOS Publication Proposal Form (TPPF)

Please submit the completed form via THAOS Website (www.THAOS.net) or sent to THAOS@pfizer.com

Part I: Basic Information

Date of Submission:
Proposal Working Title:

Proposal Author:
Name:
Institution (w/ department):
Phone:
Fax:
E-mail:

Contributors/Co-author(s):
Name:
E-mail:
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02 May 2013 Confidential THAOS
Version 1.1
E-mail:

Publication format:  
☐ Abstract  ☐ Poster  
☐ Manuscript  ☐ Slide deck  
☐ Other (specify):

Publication venue:  
☐ Meeting  ☐ Journal  
☐ Other (specify):

Publication submission deadline:
Review PPI list, and confirm whether this proposal conflicts and/or overlaps with other approved THAOS publications?

☐ No conflict with other THAOS publication proposals  
☐ Yes, potential conflict identified. Please specify PPI numbers:

Note:

Subsequent presentations of THAOS data (symposia, posters, slide sets, internet posting, internal newsletters, lay summaries for non-media use, online sessions, etc.), should also be forwarded to the Board for notification and filing.

PART II: Description (no more than 3 pages, using 10 pt. Times New Roman font).

1. Hypothesis

2. Rationale and Background for Proposal

3. Brief analysis plan and methods

4. Summary/conclusion

5. References
Addendum 2

THAOS Clinical Variables for Analysis

<table>
<thead>
<tr>
<th>THAOS Database Category</th>
<th>Subcategory</th>
<th>Variable Examples</th>
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<tbody>
<tr>
<td>1. Patient information</td>
<td>Demographics</td>
<td>Birth Date</td>
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<td>Sex</td>
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<td>Ancestry</td>
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<td>2. TTR data</td>
<td>Disease history</td>
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<td>Mutation</td>
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<td>Tissue Type</td>
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<td>Amyloid Demonstrated</td>
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<td>3. Family history</td>
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<td>Inherited From</td>
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<td>4. Medical history</td>
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<td>Respiratory</td>
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<td>Psychiatric</td>
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<td>5. Follow-Up Medical history &amp; Symptoms</td>
<td>Neurologic</td>
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<td>Endocrine/Metabolic</td>
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<td>Variable Examples</td>
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<td>Psychiatric</td>
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6. General exam

- Height
- Weight
- H R
- Systolic BP
- Diastolic BP
- Karnofsky Index

7. Medication

- Indication
- Category

8. Hospitalization

- Admission Date
- Discharge Date
- Reason

9. Laboratory Data

- Haematology
  - (see THAOS screens)
- Chemistry
- Urinalysis
- Endocrine

10. Neurological Testing

- Reflex
- Pin Prick/ Light Touch
- Vibration/ Position
- Sense
- Temperature Sensation
- Motor
- Nerve Conduction Study

11. Cardiovascular Testing

- ECG
- Echocardiogram
- 6 Minute Walk Test
- Holter
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<tr>
<th>THAOS Database Category</th>
<th>Subcategory</th>
<th>Variable Examples</th>
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<td>12. Renal</td>
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<td>13. Ophthalmic</td>
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<td>14. Body Composition</td>
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<td>15. Transplant History</td>
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<td>(see THAOS screens)</td>
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<td>16. Final Visit/ Death</td>
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<td>17. EQ-5D questionnaire</td>
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<td>18. Norfolk QoL-DN</td>
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Addendum 3

THAOS Publications and Presentations Master List (as of May 2013)

Manuscripts:


Posters:

<table>
<thead>
<tr>
<th>Congress</th>
<th>Abstract</th>
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<p>| ISA 2012 | Suhr OB, on behalf of the THAOS Investigators. Baseline Demographics and Clinical Characteristics in THAOS—the Transthyretin Amyloidosis Outcomes Survey. |
| ISA 2012 | Rapezzi C, Maurer MS, on behalf of the THAOS Investigators. Relationship between age at symptom onset and left ventricular wall thickness in ATTR amyloid – THAOS survey. |
| ISA 2012 | Coelho T, Maurer MS, Waddington Cruz M, on behalf of the THAOS Investigators. Baseline profile of patients undergoing tafamidis treatment in THAOS – the Transthyretin Amyloidosis Outcomes Survey. |
| EFNS 2012 | Coelho T, Conceição I, Planté-Bordeneuve V, Waddington Cruz M, on behalf of the THAOS investigators. Description of Neuropathic Symptoms Reported by ATTR Patients in THAOS—the Transthyretin Amyloidosis Outcomes Survey. |
| EFNS 2012 | Barbosa da Silva R, Waddington Cruz M, Planté-Bordeneuve V, on behalf of the THAOS investigators. Follow-up of Transthyretin Amyloidosis Patients With Liver Transplants or Receiving Tafamidis Treatment as Documented in THAOS—the Transthyretin Amyloidosis Outcomes Survey. |
| EFNS 2012 | Coelho T, on behalf of the THAOS investigators. Baseline Demographics and Clinical Characteristics in THAOS—the Transthyretin Amyloidosis Outcomes Survey. |</p>
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<th>Conference</th>
<th>Title</th>
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<tbody>
<tr>
<td>EFNS 2012</td>
<td>Waddington Cruz M, on behalf of the THAOS investigators. Nerve Conduction, Neurologic Assessment, and Quality of Life in Symptomatic Patients Enrolled in THAOS—the Transthyretin Amyloidosis Outcomes Survey.</td>
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<td>ABN 2012</td>
<td>Waddington Cruz M, Novis S, and Barbosa da Silva R, on behalf of the THAOS investigators. Baseline demographics of Brazilian patients in THAOS, the Transthyretin Amyloidosis Outcome Survey.</td>
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<td>AHA 2012</td>
<td>Kristen A, Cheung K, Damt T, on behalf of the THAOS investigators. Brain natriuretic peptides in patients with transthyretin amyloidosis - report from the Transthyretin Amyloidosis Outcome Survey (THAOS).</td>
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<td>DGN 2012</td>
<td>Hund E, on behalf of the THAOS investigators. Transthyretin-associated Familial Amyloid Polyneuropathy – Baseline Demographics and Clinical Characteristics in THAOS – the Transthyretin Amyloidosis Outcomes Survey.</td>
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<td>ESC 2012</td>
<td>Rapezzi C, on behalf of the THAOS investigators. THAOS: TranstHyretin Amyloidosis Outcomes Survey: an International Registry.</td>
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<tr>
<td>AAN 2013</td>
<td>Cardoso M, Coelho T, Mundayat R, on behalf of the THAOS Investigators. Overview of Patient Demographics and Clinical Characteristics in THAOS—the Transthyretin Amyloidosis Outcomes Survey.</td>
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<td>ACC 2013</td>
<td>Pacemaker Use in Patients with Transthyretin Amyloidosis in THAOS—The Transthyretin Amyloidosis Survey (A. Garan, M. Maurer, O. Suhr, R. Mundayat, on behalf of the THAOS Investigators)</td>
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<tr>
<td>ACC 2013</td>
<td>Cardiac Biomarkers in Patients With Transthyretin Amyloidosis as Documented in THAOS—The Transthyretin Amyloidosis Survey (M. Maurer, A. Kristen, C. Rapezzi, O. Suhr, S. Kolluri, T. Damy on behalf of the THAOS Investigators)</td>
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<td>ACC 2013</td>
<td>Defining Transthyretin Amyloidosis Phenotypes in THAOS—The Transthyretin Amyloidosis Survey (M. Maurer, V. Planté-Bordeneuve, T. Coelho, R. Mundayat, O. Karayal, C. Rapezzi, on behalf of the THAOS Investigators)</td>
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<tr>
<td>SGF13</td>
<td>THAOS – The Transthyretin Amyloidosis Outcomes Survey: Gastrointestinal Manifestations in Patients with Hereditary and Wild-Type Transthyretin Amyloidosis Wixner J, Mundayat R, Karayal O, Anan I, Suhr O</td>
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<td>PNS 2013</td>
<td>THAOS: an international observatory for TTR Amyloidosis (ATTR): a new window on the disease and its treatments; Berthet K, Planté-Bordeneuve V, Mundayat R</td>
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<td>ESC 2013</td>
<td>Clinical and echocardiographic signs associated with increased interventricular thickness (IVST) due to TTR related amyloidosis; Damy T, Plante-Bordeneuve V, Karayal O, Mundayat R, Kristen AV</td>
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<td>HFSA2013</td>
<td>Differences in Transthyretin Amyloidosis between the United States and the Rest of the World: A report from the Transthyretin Amyloid Outcome Survey (THAOS); Maurer M, Falk R, Kristen A, Damy T, Rapezzi C, Planté-Bordeneuve V, Coelho T, Mundayat R, Suhr O</td>
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**Platform Presentations:**