International Clinical Trials Workshop

May 19th – 20th,

2017

Workshop Evaluation Report

Athens, Greece

ASCO® International

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Executive Summary

ICTW Greece 2017

Summary:

- 2-day workshop on clinical research skills for clinicians with limited research experience
- 36 attendees: generally residents/fellows, oncologists, and nurses
- 34 completed the post-workshop evaluation

Comments:

- The percentage of respondents who agreed or strongly agreed that the educational objectives had been met was in some cases much lower than the average for all ICTWs. This is due to the large number of respondents who selected "neutral" on some items.

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Course Outcomes – One Year Later

100% of respondents reported making at least one change to their work based on what they learned in the workshop.

76% reported using best practices in research implementation.

63% reported improved design and analysis of clinical trial.

69% reported increased ability to undertake other forms of research.

63% reported increased participation in research.

94% reported increased ability to evaluate evidence from the medical literature.

19% reported interacting with another researcher whom they met at the workshop in the past year.

44% reported receiving advice or mentoring for their research activities as a result of attending the workshop.

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Introduction

The American Society of Clinical Oncology is pleased to have partnered with the Hellenic Society of Medical Oncology to present an International Clinical Trials Workshop from May 19th – 20th in Athens, Greece.

Thirty-six residents/fellows, oncologists, nurses, and others attended ICTW Greece. This two-day workshop provided the basics of clinical trial methodology for oncologists and fellows with limited research experience and no formal training in ICH GCP.

Workshop Objectives

The objectives of the ICTW are to:

1. Further best practices in the implementation of research
2. Increase understanding of how clinical trials are designed and analyzed (Phase 0-IV)
3. Increase understanding of how to undertake other forms of clinical research
4. Encourage young investigators to do research
5. Increase ability to evaluate evidence from medical literature
6. Provide networking opportunities for young investigators
7. Provide mentorship opportunities for young investigators

Evaluation Plan Overview

1.) On-site evaluation form

Attendees were asked to complete a written workshop evaluation on the last day of the workshop. Of the 36 participants who attended, 34 completed the evaluation form (response rate: 94 percent). Results to the Open-Ended Questions are in Appendix 2.

2.) Online follow-up survey

As part of the follow-up for the course, an online survey was sent to 33 participants for whom a valid email address was available. Sixteen recipients responded to the survey, a response rate of 48 percent (44 percent of all participants).

Attendee Demographics

There were 36 attendees at ICTW Greece. Demographic data was collected via the evaluation form, completed by 34 people. Generally, respondents were fellows/residents, oncologists and nurses who spend more than half their professional time working with patients, and more than 75 percent of their time working on cancer-related issues. Fifty-three percent of respondents said that they spent half or less of their practice time working on clinical research. Respondents had on average 6.4 years of experience in their profession. Seventy-seven percent of respondents said that they had assisted with research trials in the past, and 72 percent said that they had submitted an abstract or article for publication prior to attending the course.

Figure 1: Attendee Demographics

Profession	On-site		Follow-up	
	n	%	n	%
Medical fellow/resident	10	29%	4	25%
Medical/clinical oncologist	9	26%	3	19%
Nurse	4	12%	2	13%
Data Manager/Research Assistant	3	9%	4	25%
Study Coordinator	2	6%	0	0%
Data manager	2	6%	0	0%
Research Assistant	2	6%	0	0%
Other	2	6%	3	19%
Total	**34**	**100%**	**16**	**100%**

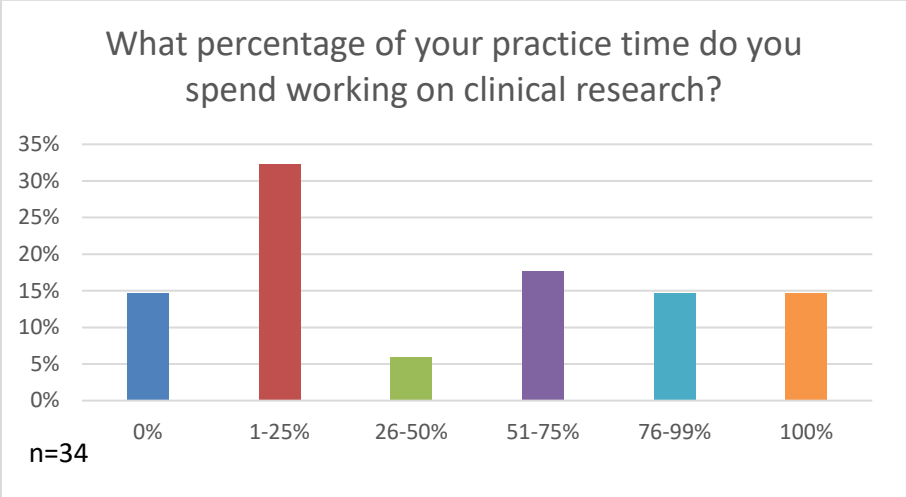
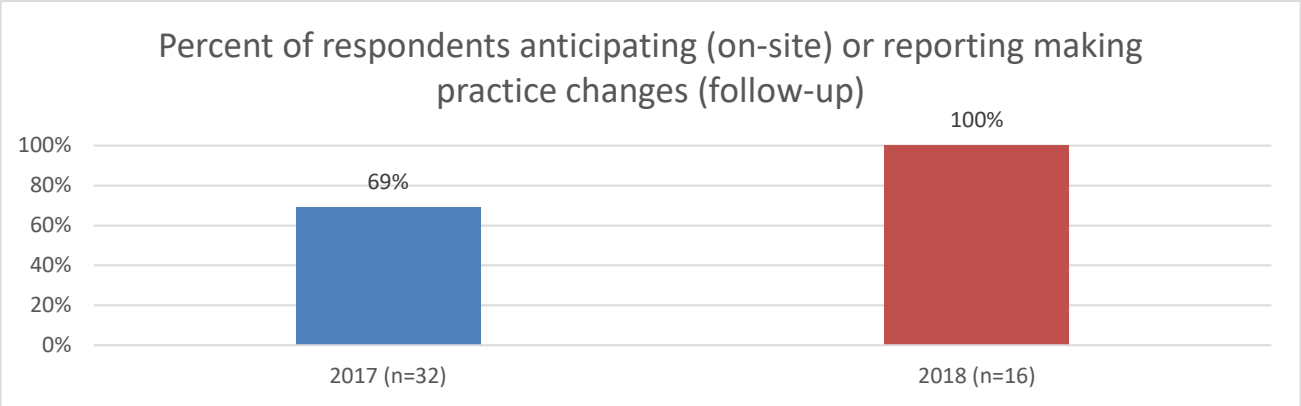


Figure 2: Roughly half of respondent spend up to half of their practice time working on clinical research

Evaluation Results: Practice Changes



On-site Results

Respondents were asked if they would make a practice change based on information learned at the course. Sixty-nine percent of respondents said they planned to do something differently. This is similar to the average for ICTWs, 75 percent. The intended changes included:

- More critical evaluation of the literature (3)
- Promote clinical trials to patients and/or colleagues (3)
- Better eCRF management (2)
- Comply with GCP guidelines (2)
- Implement patient accrual strategies (2)

One-year Impact Assessment

One year later, 10 of 16 respondents to the impact assessment said that their participation in research had increased since attending the workshop. In addition, all respondents said that they had made a practice change based on what they learned at the workshop. The most frequently reported changes were:

- Adhered to roles and responsibilities of the research team (14)
- Applied principles of patient safety in clinical research (13)
- Adhered to regulations concerning clinical research (12)
- Gathered and reported data according to global standards (12)

Evaluation Results: By Workshop Objective

Objectives	ICTW Greece On-Site	ICTW Greece Follow-up	ICTW Average	Practice Changes
1. Further best practices in the implementation of research*	85%	76%	80%	• Adhered to roles and responsibilities of the research team (14) • Applied principles of patient safety in clinical research (13) • Adhered to regulations concerning clinical research (12) • Gathered and reported data according to global standards (12) • Applied ethical principles of clinical research (10)
2. Increase understanding of how clinical trials are designed and analyzed (Phase 0-IV)**	46%	63%	47%^	
3. Increase understanding of how to undertake other forms of clinical research	No data	69%	61%^	
4. Encourage young investigators to do research	No data	63%	55%	
5. Increase ability to evaluate evidence from medical literature	No data	94%	89%^	
6. Provide networking opportunities for young investigators	71%	19%	11%^	
7. Provide mentorship opportunities for young investigators	Follow-up only	44%	37%^	

*Average of: ethics, regulatory issues, patient safety, global standards for data, and roles and responsibilities of research team.

**On-site: average of writing a protocol and statistics.

^ICTW average result is from one other workshop.

Summary & Conclusions

Sixteen people responded to the impact assessment, representing just under half of all workshop participants. All respondents said that they had made at least one change to their work as a result of what they learned at ICTW Greece.

The workshop appears to have been most successful in increasing participants' ability to evaluate evidence from the medical literature, with all but one respondent saying that they were better able to do so after attending ICTW Greece; this is comparable to the results of another recent ICTW for which data are available. The objectives of furthering best practices in research implementation and undertaking other forms of research appear to have been somewhat successful, with 76 and 69 percent of respondents reporting using skills that they learned or an improved ability, respectively. In addition, 63 percent of respondents reported that their involvement with research had increased, and that their design and analysis of clinical trials had improved as a result of what they learned at the workshop.

Finally, Forty-four percent of respondents said that they had received some advice or mentoring for their research activities as a result of attending the workshop. However, only 19 percent of respondents said that they had interacted with another researcher whom they met at ICTW Greece. These results appear to be somewhat contradictory; it is possible that the advice or mentoring reported was received on-site, perhaps in discussion with faculty or other attendees rather than after the event concluded. Both results are similar to the follow-up results of another workshop. No respondents provided any comments regarding their interaction with other researchers or mentoring experience. The phrasing of the question will be reviewed for future impact assessments.

Appendix 1: Impact Assessment Results

In the past 12 months my involvement with research has:	Responses	
Increased	63%	10
Stayed the same	25%	4
Decreased	6%	1
I am not working in research	6%	1

What involvement have you had in clinical research in the past 12 months? (please check all that apply)	Responses	
I have assisted with research trials	100%	14
I have led research trials	7%	1
I have evaluated protocols proposed to my institution	7%	1
I have developed protocols	14%	2
	Answered	**14**

As a result of what you learned at ICTW Greece, are you better able to:	Yes		No		Total
Evaluate evidence from the medical literature	94%	15	6%	1	16
Evaluate cost-effectiveness	69%	9	31%	4	13
Write a protocol	38%	5	62%	8	13
Publish your research	67%	10	33%	5	15

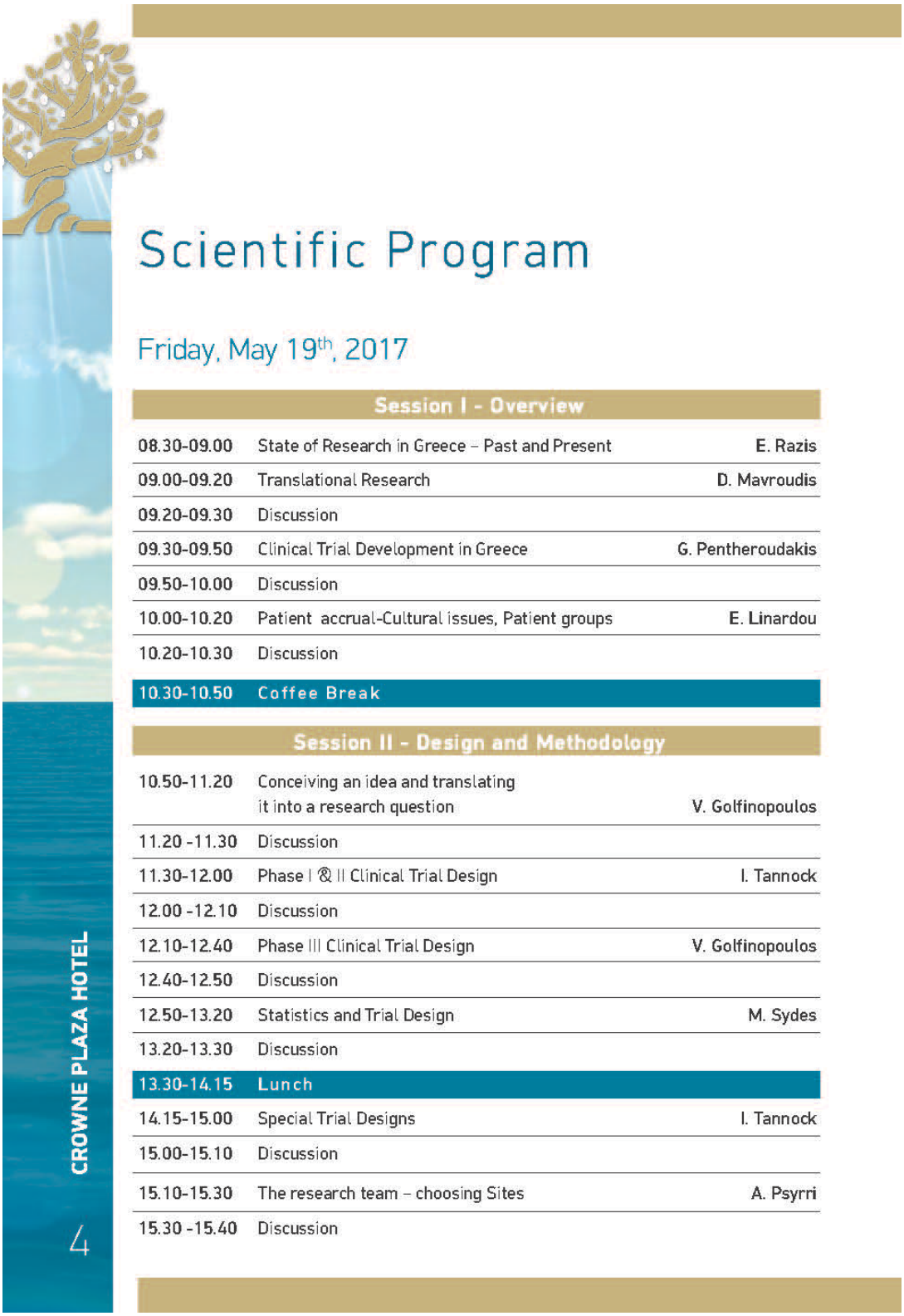
In the past year, have you made any changes to your work as a result of what you learned at the ICTW?	Yes		No	
Applied ethical principles of clinical research	63%	10	38%	6
Adhered to regulations concerning clinical research	75%	12	25%	4
Gathered and reported data according to global standards	75%	12	25%	4
Applied principles of patient safety in clinical research	81%	13	19%	3
Improved design and analysis of clinical trials	63%	10	38%	6
Adhered to roles and responsibilities of the research team	88%	14	13%	2
Other changes and comments:				

In the past year, have you interacted with another researcher whom you met at ICTW Greece?	Responses	
Yes	19%	3
No	81%	13

As a result of attending the workshop, have you received any advice or mentoring for your research activities?	Responses	
Yes	44%	7
No	56%	9

What is your profession?	Responses	
Medical/Clinical Oncologist	19%	3
Medical Resident/Fellow	25%	4
Nurse	13%	2
Data Manager	25%	4
Other (please specify)	19%	3

Appendix 2: Workshop Agenda



Scientific Program

Friday, May 19th, 2017

Session I - Overview		
08.30-09.00	State of Research in Greece – Past and Present	E. Razis
09.00-09.20	Translational Research	D. Mavroudis
09.20-09.30	Discussion	
09.30-09.50	Clinical Trial Development in Greece	G. Pentheroudakis
09.50-10.00	Discussion	
10.00-10.20	Patient accrual-Cultural issues, Patient groups	E. Linardou
10.20-10.30	Discussion	
10.30-10.50	Coffee Break	
Session II - Design and Methodology		
10.50-11.20	Conceiving an idea and translating it into a research question	V. Golfinopoulos
11.20 -11.30	Discussion	
11.30-12.00	Phase I & II Clinical Trial Design	I. Tannock
12.00 -12.10	Discussion	
12.10-12.40	Phase III Clinical Trial Design	V. Golfinopoulos
12.40-12.50	Discussion	
12.50-13.20	Statistics and Trial Design	M. Sydes
13.20-13.30	Discussion	
13.30-14.15	Lunch	
14.15-15.00	Special Trial Designs	I. Tannock
15.00-15.10	Discussion	
15.10-15.30	The research team – choosing Sites	A. Psyrri
15.30 -15.40	Discussion	

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15.40-16.00	Cooperative groups (national and international)	A. Eniu
16.00-16.10	Discussion	
16.10-16.30	Value and Clinical Benefit Studies	A. Eniu, I. Tannock
16.30-16.40	Discussion	
16.40 - 17.00	Coffee Break	

Session III - Break out Sessions

17.00-18.30	Which design for which question: Fundamental biostatistical concerns.	
	• Clinical Benefit and Cost Effectiveness (Value Framework)	A. Eniu
	• Observational and QOL studies	I. Tannock
	• Biomarkers and translational research	V. Golfinopoulos
	• Smaller populations	M. Sydes
	• Trial design: learning through a published paper I	E. Razis
	• Trial design: learning through a published paper II	G. Mountzios

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Saturday, May 20th, 2017

Session IVA - Logistics		
08.30-08.50	ICF / CRF Technology – Novel ways that can assist in data capture	S. Romboli
08.50-09.00	Discussion	
09.00-09.20	GCP/ Ethics and the Informed Consent	E. Saloustros
09.20-09.30	Discussion	
09.30-09.50	Funding and Budget	V. Golfinopoulos
09.50-10.00	Discussion	
Session IVB - Running the Protocol		
10.00-10.20	Regulations and SAE	A. Goudopoulou
10.20-10.30	Discussion	
10.30-10.50	Site Monitoring-Audits	V. Golfinopoulos
10.50-11.00	Discussion	
11.00-11.20	Coffee Break	
Session V - Publication		
11.20-11.40	Presenting, Writing and Publishing	G. Mountzios
11.40-11.50	Discussion	
11.50-12.10	What can go wrong: Bias, under powered studies, early stopping etc	M. Sydes
12.10-12.20	Discussion	
12.20-12.40	Critical Evaluation of the literature	I. Tannock
12.40-12.50	Discussion	
12.50-13.05	Data Sharing	M. Sydes
13.05-13.15	Discussion	
13.15-14.00	Lunch	
Session VI - Break out Sessions		
14.00-15.30	• Clinical Benefit and Cost Effectiveness (Value Framework)	A. Eniu
	• Observational and QOL studies	I. Tannock
	• Biomarkers and translational research	V. Golfinopoulos
	• Smaller populations	M. Sydes
	• Trial design: learning through a published paper I	E. Razis
	• Trial design: learning through a published paper II	G. Mountzios
15.30 – 16.30	Presentations by the groups	
16.30 – 17.30	Discussion & Closure	

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