International Clinical Trials Workshop

March 23rd – 25th

2017

Workshop Evaluation Report

Montevideo, Uruguay

ASCO® International

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Executive Summary

ICTW Uruguay 2017

Summary:

- 3-day workshop on clinical research skills for clinicians with limited research experience
- 73 attendees: generally oncologists, residents/fellows, and nurses
- 51 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

89% of respondents reported making at least one change to their work based on what they learned in the workshop.

67% reported using best practices in research implementation.

47% reported improved design and analysis of clinical trial.

61% reported increased ability to undertake other forms of research.

42% reported increased participation in research.

89% reported increased ability to evaluate evidence from the medical literature.

11% reported interacting with another researcher whom they met at the workshop in the past year.

37% 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 Federación Latinoamericana de Sociedades de Cancerología (FLASCA), to present an International Clinical Trials Workshop from March 23rd – 25th in Montevideo, Uruguay.

Seventy-three oncologists, residents, nurses, and others attended ICTW Uruguay. This three-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 73 participants who attended, 51 completed the evaluation form (response rate: 70 percent).

2.) Online follow-up survey

As part of the follow-up for the course, an online survey was sent to 66 participants for whom a valid email address was available. Nineteen recipients responded to the survey, a response rate of 29 percent (26 percent of all participants).

Attendee Demographics

There were 73 attendees at ICTW Uruguay. Demographic data was collected via the evaluation form, completed by 51 people. Generally, respondents were oncologists, fellows/residents and nurses who spend 25 percent or less of their time working in clinical research, more than half their professional time working with patients, and more than half of their time working on cancer-related issues. Respondents had on average 7.1 years of experience in their profession.

Profession	On-Site		Follow-up	
	n	%	n	%
Medical/Clinical Oncologist	16	31%	12	63%
Medical Fellow/Resident	13	25%	5	26%
Nurse	8	16%	1	5%
General Doctor	3	6%	0	0%
Industry Representative	3	6%	0	0%
Gynecologist	2	4%	0	0%
Other	6	12%	1	5%
Total	51	100%	19	100%

Figure 1: Attendee Demographics

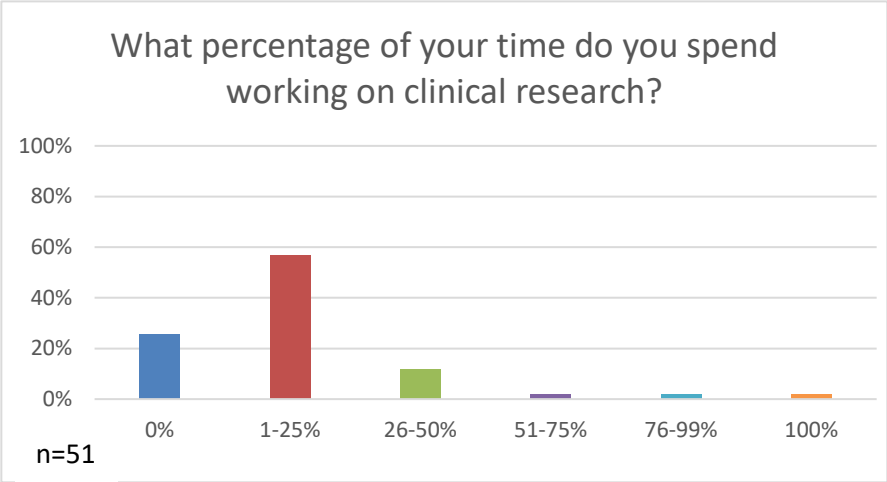
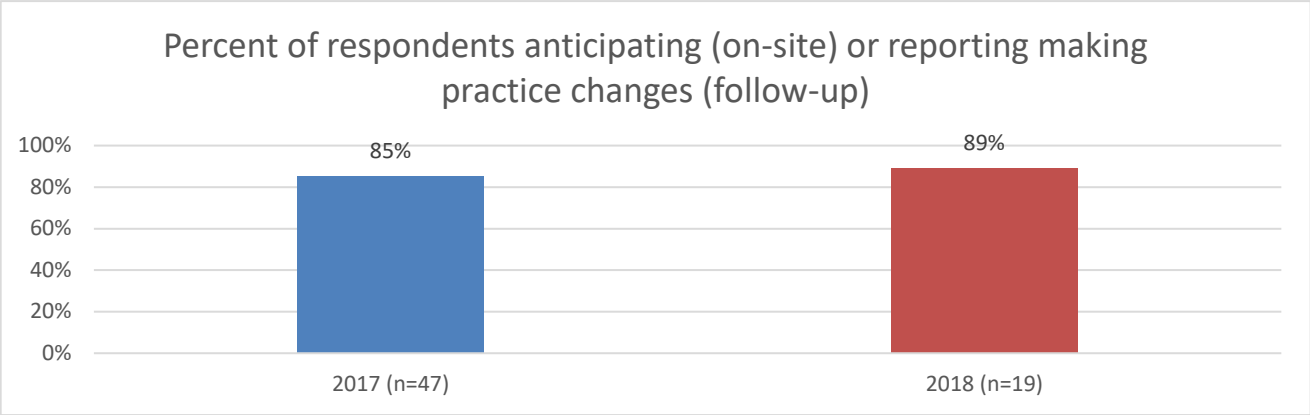


Figure 2: Majority of respondents spend one quarter or less of their time working in clinical research

Evaluation Results: Practice Changes



On-site Results

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

- Participate in research (10)
- More critical reading of literature (4)
- Changes to patient care based on analysis of evidence (3)
- Changes to protocol (3)
- Develop research skills (3)

One-year Impact Assessment

One year later, 42 percent of respondents to the impact assessment said that their participation in research had increased since attending the workshop. In addition, 89 percent of respondents said that they had made a practice change based on what they learned at the course; this is higher than the average for ICTWs (79 percent). The most frequently reported changes were:

- Adhered to roles and responsibilities of the research team (15)
- Applied ethical principles of 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 Uruguay On-Site	ICTW Uruguay Follow-up	ICTW Average	Practice Changes
1. Further best practices in the implementation of research*	76%	67%	82%	• Adhered to roles and responsibilities of the research team (15) • Applied ethical principles of clinical research (13) • Adhered to regulations concerning clinical research (12) • Gathered and reported data according to global standards (12) • Applied principles of patient safety in clinical research (11)
2. Increase understanding of how clinical trials are designed and analyzed (Phase 0-IV)**	35%	47%	63%^	
3. Increase understanding of how to undertake other forms of clinical research***	54%	61%	69%^	• 9 respondents said that they are better able to evaluate cost-effectiveness. • 14 respondents said that they are better able to perform and support a systematic review.
4. Encourage young investigators to do research	No data	42%	57%	
5. Increase ability to evaluate evidence from medical literature	73%	89%	94%^	
6. Provide networking opportunities for young investigators	73%	11%	19%^	
7. Provide mentorship opportunities for young investigators	Follow-up only	37%	44%^	

*Average of: ethics, regulatory issues, patient safety, global standards for data, and roles and responsibilities of research team.
**On-site: writing a protocol.
^ICTW average result is from one other workshop.

Summary & Conclusions

Nineteen people responded to the impact assessment, representing 26 percent of workshop participants. The low response rate limits the generalizability of the results. Overall, 89 percent of respondents reported making practice changes based on what they learned in the workshop, which is higher than the average for ICTWs.

The workshop appears to have been most successful in increasing participants' ability to evaluate evidence from the medical literature, with 89 percent of respondents saying that they were better able to do so after attending ICTW Uruguay; 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 67 and 61 percent of respondents reporting using skills that they learned or an improved ability, respectively.

The results for other workshop objectives were less successful. A below average percentage of respondents reported that their participation in research had increased since attending the workshop (42 versus 57 percent). In addition, just under half reported improvement in their ability to design and analyze a trial; this is higher than the percentage of respondents on-site who reported being better able to write a protocol after the workshop, but lower than the follow-up results of another recent workshop.

In addition, thirty-seven 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 11 percent of respondents said that they had interacted with another researcher whom they met at ICTW Uruguay. 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	42%	8
Stayed the same	42%	8
Decreased	0%	0
I am not working in research	16%	3

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	63%	10
I have led research trials	25%	4
I have evaluated protocols proposed to my institution	38%	6
I have developed protocols	38%	6

As a result of what you learned at ICTW Uruguay, are you better able to:	Yes		No		Total
Evaluate evidence from the medical literature	89%	17	11%	2	19
Evaluate cost-effectiveness	47%	9	53%	10	19
Perform and report a systematic review	74%	14	26%	5	19

In the past year, have you made any changes to your work as a result of what you learned at the ICTW?	Yes		No		Total
Applied ethical principles of clinical research	68%	13	31%	6	19
Adhered to regulations concerning clinical research	63%	12	37%	7	19
Gathered and reported data according to global standards	63%	12	37%	7	19
Applied principles of patient safety in clinical research	61%	11	39%	7	18
Improved design and analysis of clinical trials	47%	9	53%	10	19
Adhered to roles and responsibilities of the research team	79%	15	21%	4	19
Other changes and comments:					0

If you did not make any changes to your work, why not?	Responses	
The materials presented were not relevant to my work	0%	0
I have not had the opportunity to apply what I learned to my work	50%	1
I am not working in research	50%	1
Other, please specify	0%	0

In the past year, have you interacted with another researcher whom you met at ICTW Uruguay?	Responses	
Yes	11%	2
No	89%	17

As a result of attending the workshop, have you received any advice or mentoring for your research activities?	Responses	
Yes	37%	7
No	63%	12

What is your profession?	Responses	
Medical/Clinical Oncologist	63%	12
Medical Resident/Fellow	26%	5
Nurse	5%	1
General Doctor	0%	0
Other (please specify)	5%	1

Appendix 2: Workshop Agenda

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Universidad de la República

NCI
National Cancer Institute

ONS
Oncology Nursing Society

DAY 1: THURSDAY, 23 MARCH

Evidence-based medicine, Cost-effectiveness and Clinical benefit

08.00 – 08.30 **Registration**

08.30 – 08.45 **Welcome and Introduction:**

08.45 – 09.05 **Evidence-based medicine. How to evaluate evidence from the medical literature**
Chair: *Dr. Enrique Barrios*
Speaker: *Dra. Giselle Tomasso*

09.05 – 09.25 **How to perform and report a systematic review**
Chair: *Dr. Oscar Gianneo*
Speaker: *Dra. Alicia Alemán*

09.25 – 09.45 **The difference between statistical significance and clinical importance**
Chair: *Dr. Pedro Kasdorf*
Speakers: *Dra. Susan Hilsenbeck (USA), Dra. Gail Eckhardt (USA)*

09.45 – 10.05 **Increasing role of biomarkers**
Chair: *Dr. Gabriel Krygier*
Speaker: *Dra. Gail Eckhardt (USA)*

10.05 – 10.25 **Panel/Discussion**
Chairs: *Dr. Oscar Gianneo, Dr. Alvaro Luongo*

10.25 – 10.45 **Coffee Break**

10.45 – 11.15 **Reading the literature on clinical trials with a critical eye: learning from the mistakes of others**
Chair: *Dra. Lucía Delgado*
Speaker: *Dr. Ian Tannock (Canadá)*

11.15 – 12.45 **Breakout group session 1: "Critical appraisal"**
Facilitators: *Dr. Ian Tannock (Canadá), Dra. Susan Hilsenbeck (USA), Dra. Gail Eckhardt (USA), Dr. Mauricio Cuello, Dr. Luis Ubillos, Dra. Cecilia Castillo, Dra. Giselle Tomasso, Dr. Enrique Barrios, Dra. Bettina Müller (Chile), Dra. Lucía Delgado*

12.45 - 13.45 **Break**

13.45 - 14.05 **Evaluation of toxicity; under-reporting of harm**
Chair: *Dr. Juan Lacava (Argentina)*
Speaker: *Dr. Thomas Gross (USA)*

14.05 – 14.25 **ESMO, ASCO and NCCN initiatives to measure clinical benefit or value**
Chair: *Dra. Bettina Müller (Chile)*
Speaker: *Dr. Ian Tannock (Canadá)*

14.25 – 14.45 **Strategies for managing patients who cannot afford the best evidence-based treatment**
Chair: *Dr. Mauricio Cuello*
Speaker: *Dr. Thomas Gross (USA)*

14.45 - 15.05 **How to evaluate cost-effectiveness**
Chair: *Dra. Alicia Alemán*
Speaker: *Dr. Ian Tannock (Canadá)*

15.05 - 15.20 **Panel/Discussion**
Chairs: *Dra. Bettina Müller (Chile), Dr. Mauricio Cuello*

15.20 - 17.00 **Breakout group session 2 (with coffee): "Cost effectiveness and clinical value"**
Facilitators: *Dr. Ian Tannock (Canadá), Dr. Thomas Gross (USA), Dra. Alicia Alemán, Dra. Bettina Müller (Chile), Dr. Mauricio Cuello, Dr. Juan Lacava (Argentina), Dra. Cecilia Castillo, Dr. Luis Ubillos, Dra. Lucía Delgado*

17.00 – 17.30 **Plenary: Articles on clinical trials / cost effectiveness**
Chairs: *Dr. Ian Tannock (Canadá), Dra. Lucía Delgado, Dr. Thomas Gross (USA)*

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DAY 2: FRIDAY, 24 MARCH

Clinical Trials Evaluating New Therapies

08.30 – 08.50 **Epidemiology of Cancer in Uruguay and South American Countries**
Chair: *Dra. Graciela Sabini*
Speaker: *Dr. Enrique Barrios*

08.50 – 09.10 **Clinical trials in Uruguay and neighboring countries- Importance and main challenges**
Chair: *Dr. Juan Lacava (Argentina)*
Speaker: *Dra. Lucía Delgado*

09.10 – 09.30 **Clinical trials in Uruguay - Importance and main challenges**
Chair: *Dr. Mauricio Cuello*
Speaker: *Dr. Jorge Basso (Ministry of Health, Uruguay)*

09.30 – 09.50 **Clinical Trials in Uruguay – Importance and main challenges**
Chair: *Dr. Alberto Viola*
Speaker: *Dra. Deyanira Dolinsky*

09.50 – 10.15 **Panel/Discussion**
Chairs: *Dr. Juan Lacava (Argentina), Dra. Lucía Delgado*

10.15 – 10.40 **Coffee Break**

10.40 – 11.00 **Introduction to clinical trials; how to explain them to patients**
Chair: *Dr. Mario Varangot*
Speaker: *Lic. Carmen Jacobs (USA)*

11.00 – 11.20 **Phase I protocol designs**
Chair: *Dr. Luis Ubillos*
Speaker: *Dra. Gail Eckhardt (USA)*

11.20 - 11.40 **Phase II protocol designs**
Chair: *Dra. Cecilia Castillo*
Speaker: *Dra. Gail Eckhardt (USA)*

11.40 – 12.00 **Statistical issues in Phase I and II trials**
Chair: *Ing. Rafael Alonso*
Speaker: *Dra. Susan Hilsenbeck (USA)*

12.00 – 12.20 **International standards of informed consent and Good Clinical Practice**
Chair: *Dra. Bettina Müller (Chile)*
Speaker: *Lic. Carmen Jacobs (USA)*

12.20 – 12.50 **Panel/Discussion**
Chairs: *Dra. Bettina Müller (Chile), Dra. Marta Aghazarián*

12.50 – 13.50 **Break**

13.50 – 14.10 **Phase III protocol designs**
Chair: *Dr. Juan Lacava (Argentina)*
Speaker: *Dr. Ian Tannock (USA)*

14.10 – 14.30 **Statistical issues in Phase III trials**
Chair: *Ing. Rafael Alonso*
Speaker: *Dra. Susan Hilsenbeck (USA)*

14.30 - 14.50 **Responsibilities of the study team (including design and completion of case report forms [CRFs], toxicity reporting)**
Chair: *Dr. Robinson Rodríguez*
Speaker: *Lic. Carmen Jacobs (USA)*

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14.50 – 15.10 **Site management, monitoring and audit in clinical trials**
Chair: *Dra. Isabel Alonso*
Speaker: *Lic. Carmen Jacobs (USA)*

15.10 – 16.30 **Breakout group session 3 (with coffee): Desing of clinical trials**
Facilitators: *Lic. Carmen Jacobs (USA), Dr. Ian Tannock (Canadá), Dra. Susan Hilsenbeck (USA), Dr. Juan Lacava (Argentina), Ing. Rafael Alonso, Dr. Robinson Rodriguez, Dra. Isabel Alonso, Dr. Luis Ubillos, Dra. Bettina Müller (Chile), Dr. Mauricio Cuello, Dra. Cecilia Castillo*

16.30 – 17.30 **Plenary presentation of 2 clinical trial concepts and one trial management issue**
Chairs: *Dr. Ian Tannock (Canadá), Dra. Lucía Delgado, Dr. Thomas Gross (USA)*

DAY 3: SATURDAY, 25 MARCH

Observational studies and other types of clinical research

08.30 – 09.00 **Alternative types of clinical research: observational studies, quality of life, prognosis etc.**
Chair: *Dr. Sebastian Ximénez*
Speaker: *Dr. Ian Tannock (Canada)*

09.00 – 09.20 **Principles of ethics in clinical research**
Chair: *Dr. Hugo Rodríguez Almada*
Speaker: *Dr. Thomas Gross (USA)*

09.20 – 09.40 **How can you write a protocol**
Chair: *Dra. Natalia Camejo*
Speaker: *Dra. Gail Eckhardt (USA)*

09.40 - 10.00 **Publishing and presenting your research findings**
Chair: *Dr. Diego Touyá*
Speaker: *Dr. Ian Tannock (Canada)*

10.00 – 10.20 **Mentorship and funding**
Chair: *Dr. Juan Lacava (Argentina)*
Speaker: *Dr. Mauricio Cuello*

10.20 – 12.00 **Breakout group session 4 (with coffee): Observational study**
Facilitators: *Dr. Ian Tannock (Canadá), Dr. Thomas Gross (USA), Dra. Gail Eckhard (USA), Dr. Luis Ubillos, Dra. Cecilia Castillo, Dr. Mauricio Cuello, Dr. Diego Touyá, Dr. Juan Lacava (Argentina)*

12.00 – 12.20 **Presentation of sample protocols by the small groups**

12.20 – 12.50 **Plenary presentation of 2 concepts for observational studies**
Chairs: *Dra. Cecilia Castillo, Dra. Noelia Silveyra, Dr. Luis Ubillos*

12.50 – 13.00 **Closing Remarks**

13.00 **End of the Workshop - Certification**