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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.

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.
- 42% reported increased participation in research.
- 67% reported using best practices in research implementation.
- 89% reported increased ability to evaluate evidence from the medical literature.
- 47% reported improved design and analysis of clinical trial.
- 11% reported interacting with another researcher whom they met at the workshop in the past year.
- 61% reported increased ability to undertake other forms of research.
- 37% reported receiving advice or mentoring for their research activities as a result of attending the workshop.
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.

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

Figure 1: Attendee Demographics

What percentage of your time do you spend working on clinical research?

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>7</td>
<td>1-25%</td>
</tr>
<tr>
<td>26-50%</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>51-75%</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>76-99%</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>100%</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

n=51

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

<table>
<thead>
<tr>
<th>Objectives</th>
<th>ICTW Uruguay On-Site</th>
<th>ICTW Uruguay Follow-up</th>
<th>ICTW Average</th>
<th>Practice Changes</th>
</tr>
</thead>
</table>
| 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%^         | 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. |
| 3. Increase understanding of how to undertake other forms of clinical research*** | 54%                  | 61%                    | 69%^         | ? |
| 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:**

<table>
<thead>
<tr>
<th></th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased</td>
<td>42%</td>
</tr>
<tr>
<td>Stayed the same</td>
<td>42%</td>
</tr>
<tr>
<td>Decreased</td>
<td>0%</td>
</tr>
<tr>
<td>I am not working in research</td>
<td>16%</td>
</tr>
</tbody>
</table>

**What involvement have you had in clinical research in the past 12 months? (please check all that apply)**

<table>
<thead>
<tr>
<th></th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have assisted with research trials</td>
<td>63%</td>
</tr>
<tr>
<td>I have led research trials</td>
<td>25%</td>
</tr>
<tr>
<td>I have evaluated protocols proposed to my institution</td>
<td>38%</td>
</tr>
<tr>
<td>I have developed protocols</td>
<td>38%</td>
</tr>
</tbody>
</table>

**As a result of what you learned at ICTW Uruguay, are you better able to:**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate evidence from the medical literature</td>
<td>89%</td>
<td>17%</td>
<td>19</td>
</tr>
<tr>
<td>Evaluate cost-effectiveness</td>
<td>47%</td>
<td>9%</td>
<td>19</td>
</tr>
<tr>
<td>Perform and report a systematic review</td>
<td>74%</td>
<td>14%</td>
<td>19</td>
</tr>
</tbody>
</table>

**In the past year, have you made any changes to your work as a result of what you learned at the ICTW?**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applied ethical principles of clinical research</td>
<td>68%</td>
<td>31%</td>
<td>19</td>
</tr>
<tr>
<td>Adhered to regulations concerning clinical research</td>
<td>63%</td>
<td>37%</td>
<td>19</td>
</tr>
<tr>
<td>Gathered and reported data according to global standards</td>
<td>63%</td>
<td>37%</td>
<td>19</td>
</tr>
<tr>
<td>Applied principles of patient safety in clinical research</td>
<td>61%</td>
<td>39%</td>
<td>18</td>
</tr>
<tr>
<td>Improved design and analysis of clinical trials</td>
<td>47%</td>
<td>53%</td>
<td>19</td>
</tr>
<tr>
<td>Adhered to roles and responsibilities of the research team</td>
<td>79%</td>
<td>21%</td>
<td>19</td>
</tr>
<tr>
<td>Other changes and comments:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**If you did not make any changes to your work, why not?**

<table>
<thead>
<tr>
<th></th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>The materials presented were not relevant to my work</td>
<td>0%</td>
</tr>
<tr>
<td>I have not had the opportunity to apply what I learned to my work</td>
<td>50%</td>
</tr>
<tr>
<td>I am not working in research</td>
<td>50%</td>
</tr>
<tr>
<td>Other, please specify</td>
<td>0%</td>
</tr>
</tbody>
</table>

**In the past year, have you interacted with another researcher whom you met at ICTW Uruguay?**

<table>
<thead>
<tr>
<th></th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>11%</td>
</tr>
<tr>
<td>No</td>
<td>89%</td>
</tr>
</tbody>
</table>

American Society of Clinical Oncology  
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International Affairs • international@asco.org
As a result of attending the workshop, have you received any advice or mentoring for your research activities?

<table>
<thead>
<tr>
<th></th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>37%</td>
</tr>
<tr>
<td>No</td>
<td>63%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What is your profession?</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical/Clinical Oncologist</td>
<td>63%</td>
</tr>
<tr>
<td>Medical Resident/Fellow</td>
<td>26%</td>
</tr>
<tr>
<td>Nurse</td>
<td>5%</td>
</tr>
<tr>
<td>General Doctor</td>
<td>0%</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>5%</td>
</tr>
</tbody>
</table>
Appendix 2: Workshop Agenda

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 Aleman

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

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

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

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. Lucia Delgado
   Speaker: Dr. Ian Tannock (Canada)

11.15 – 12.45  Breakout group session 1: “Critical appraisal”
   Facilitators: Dr. Ian Tannock (Canada), Dra. Susan Hilsenbeek (USA), Dra. Gail Eckhardt (USA),
   Dr. Mauricio Cuello, Dr. Luis Ubiñas, Dra. Cecilia Castillo, Dra. Giselle Tomasso,
   Dr. Enrique Barrios, Dra. Bettina Müller (Chile), Dra. Lucia 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)
   Speakers: Dr. Ian Tannock (Canada)

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 Aleman
   Speaker: Dr. Ian Tannock (Canada)

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 (Canada), Dr. Thomas Gross (USA), Dra. Alicia Aleman,
   Dra. Bettina Müller (Chile), Dr. Mauricio Cuello, Dr. Juan Lacava (Argentina),
   Dra. Cecilia Castillo, Dr. Luis Ubiñas, Dra. Lucia Delgado

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

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. Deysi Nolinsky

09:50 – 10:15 Panel/Discussion
Chair: 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: Lí. Carmen Jacobs (USA)

11:00 – 11:20 Phase I protocol designs
Chair: Dr. Luis Ulibarri
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: Lí. Carmen Jacobs (USA)

12:20 – 12:50 Panel/Discussion
Chair: Dra. Bettina Müller (Chile), Dra. Marta Aghabarán

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: Lí. Carmen Jacobs (USA)
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): Designing of clinical trials
Facilitators: Lic. Carmen Jacobs (USA), Dra. Jan Tannock (Canada), Dra. Susan Hilsenbeck (USA), Dr. Juan Lacava (Argentina), Ing. Rafael Alonso, Dr. Robinson Rodriguez, Dra. Isabel Alonso, Dr. Luis Uribos, 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 (Canada), Dra. Lucia 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. Sebastián Jiménez
Speaker: Dr. Ian Tannock (Canada)

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

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

09.40 – 10.00 Publishing and presenting your research findings
Chair: Dr. Diego Touraj
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 (Canada), Dr. Thomas Gross (USA), Dra. Gail Eckhardt (USA), Dr. Luis Uribos, Dra. Cecilia Castillo, Dr. Mauricio Cuello, Dr. Diego Touraj, 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. Nevita Silvaeyra, Dr. Luis Uribos

12.50 – 13.00 Closing Remarks

13.00 End of the Workshop - Certification