19th Conference of the International Society of Geriatric Oncology

Integrative oncology – Leaving no one behind

www.SIOGconference.org
Barriers to participation to clinical trials

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CONFLICT OF INTEREST DISCLOSURE

I have no potential conflict of interest to report
Spectrum of populations in medical experimentations

- Deprived People in experimentations
- Nazis Experimentations
- Protection of vulnerable people in clinical trials
- Helsinki declarations
- Legal rules
- Under-representation of women, minorities, children, older people

XVIII/XX century 2d world war 1964-2019
Political Actions and rules

Cour des comptes
1993

1994

1998

2003

2006

2009

2015

2017

NIH
National Institutes of Health

ICH
harmonisation for better health

FDA
U.S. Food & Drug Administration

World Health Organization

SIOG
International Society of Geriatric Oncology

Geneva, Switzerland
14-16 Nov 2019

19th Conference of the International Society of Geriatric Oncology
Integrative oncology – Leaving no one behind

Strengthening the health care workforce for older people living with cancer
Plus ça change, plus c’est la même chose.
[The more things change, the more they stay the same.]
—Jean-Baptiste Alphonse Karr (Les Guêpes, January 1849)
Geller, 2018
# Representation of Minorities and Women in Oncology Clinical Trials: Review of the Past 14 Years

Narjast Duma, Jesus Vera Aguilera, Jonas Paludo, Candace L. Hoddox, Miguel Gonzalez Velez, Yucai Wang, Konstantinos Leventakos, Joleen M. Hubbard, Aaron S. Mansfield, Ronald S. Go, and Alex A. Adjei

## Table 1. Participants in National Cancer Institute Cooperative Group Breast, Colorectal, Lung, or Prostate Cancer Therapeutic Trials, 1995-2002 (N = 76,215)*

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td><strong>Race/ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White non-Hispanic</td>
<td>64,355</td>
<td>85.6</td>
<td>83.1</td>
<td>75.7</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2,292</td>
<td>3.1</td>
<td>3.8</td>
<td>9.1</td>
</tr>
<tr>
<td>Black</td>
<td>6,882</td>
<td>9.2</td>
<td>10.9</td>
<td>10.8</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>1,446</td>
<td>1.9</td>
<td>2.0</td>
<td>3.8</td>
</tr>
<tr>
<td>American Indian/Alaskan Native</td>
<td>240</td>
<td>0.3</td>
<td>0.2</td>
<td>0.7</td>
</tr>
<tr>
<td><strong>Type of cancer</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>13,836</td>
<td>25.0</td>
<td>46,788</td>
<td>94.1</td>
</tr>
<tr>
<td>Colorectal</td>
<td>14,232</td>
<td>26.0</td>
<td>15,606</td>
<td>20.5</td>
</tr>
<tr>
<td>Lung</td>
<td>11,723</td>
<td>21.0</td>
<td>5,146</td>
<td>12.5</td>
</tr>
<tr>
<td>Pancreas</td>
<td>4,932</td>
<td>7.0</td>
<td>NA</td>
<td>63.6</td>
</tr>
<tr>
<td>Prostate</td>
<td>6,275</td>
<td>11.0</td>
<td>5,605</td>
<td>12.8</td>
</tr>
<tr>
<td>Renal</td>
<td>2,020</td>
<td>4.0</td>
<td>NA</td>
<td>34.8</td>
</tr>
<tr>
<td><strong>Age, y</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 65</td>
<td>15,619</td>
<td>64.0</td>
<td>NA</td>
<td>400.0</td>
</tr>
<tr>
<td>&gt; 65</td>
<td>11,130</td>
<td>35.0</td>
<td>NA</td>
<td>600.0</td>
</tr>
</tbody>
</table>

*Estimated for the year 2000 among adults 30 years of age and older.

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### Notes:
- Race and ethnic groups are mutually exclusive.
- Estimate for the year 2000 among adults 30 years of age and older.
Request Clinical Trial
« Cancer »
« Phase III »
« Recruiting »

N >11000
N = 3226 in Europe

N =230
N = 81 in Europe

www.clinicaltrial.org/ Access 13 November 2019
MODEL PATHWAY OF TRIAL ENROLLMENT PROCESS

Cancer diagnosis

Clinic access

Assessment of trial availability

No trial available

Clinic visit

Assessment of patient eligibility for available trial

Patient eligible

Patient ineligible

Demographic and Socioeconomic Status

Discussion of trial participation with physician

Trial discussed

Trial not discussed

Attitudinal (physician)

Trial participation offered/not offered

Trial offered

Trial not offered

Attitudinal (patient)

Patient decision

Patient agrees to participate

Patient declines to participate

Structural

577 patients over the age of 65

- 474/577 (82%) with at least one available clinical trial
- 127/474 (27%) meeting a clinical trial's eligibility criteria

- 84/127 (66%) invited to participate in a clinical trial
- 70/84 (83%) included in a clinical trial

No clinical trial recruiting (n = 103, 18%) for the tumor stage or site at the time of the therapeutic decision for a given patient in the department

**Main reasons for ineligibility** *(n = 347, 73%)*:
- 219 (63%): cancer-related factors (other than stage or site)
- 136 (39%): examination required before inclusion or overly longtime interval since examination
- 105 (30%): previous/concomitant treatments or excessively short time interval since treatment cessation
- 69 (20%): performance status (>2 or 1 depending of trial)
- 48 (14%): comorbidities
- 47 (14%): inappropriate hematologic, hepatic, or renal biomarker profile
- 36 (10%): age limitation

**Main reasons for noninvitation** *(n = 43, 34%)*:
- 18 (46%): patient-related issues (comorbidities or performance status)
- 8 (20%): trial-related issues (organizational factors in the center)
- 6 (15%): investigator's decision in view of the investigational treatment
- 6 (15%): lack of time (for the physician)

**Main reasons for noninclusion** *(n = 17)*:
- Refusal by the patient due to:
  - 4 (24%): fear of side effects
  - 4 (24%): doubt as to the treatment's efficiency
  - 3 (18%): the nature of the protocol (follow-up or additional procedures)
Figure 2. Trial availability, eligibility, invitation, and inclusion rates by age class in clinical trials.

*Significant pairwise comparisons (p < .05): 80 years vs. 65-69, 80 years vs. 70-74, 80 years vs. 75-79.

Canouï-Poitrine, The Oncologist, 2019
Ways to improve Actors of Change

- Availability
- Eligibility
- Offer
- Enrollment & Adherence

Sponsors, Ethics Committee, Investigators, Methodologists

Physicians, Research Staff

Patients
• Ways to improve:
  • Availability / Eligibility
  • Methodologists

  Sponsors, Ethics Committee, Investigators, Methodologists

  Ethics Committees, Sponsors

  ➢ Dedicated or with a sufficient Sample Size of Older Patients
  ➢ Pragmatic (PRECIS-2 Tool)
  ➢ Exclusion of Older Patients (directly or indirectly) have to be justified
  ➢ Preference/Observational Arm
Ways to improve:

- Offer Recognition of a specific task that need **Extra-time:** time to offer AND extended patient recruitment period
- Specific skills/competencies
- Therefore financial effort

Physicians may be more likely to recruit older persons into trials if:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is a specific requirement to recruit older people</td>
<td>90%</td>
</tr>
<tr>
<td>There are specific age related recruitment figures</td>
<td>90%</td>
</tr>
<tr>
<td>Payment recognises extra-work load</td>
<td>70%</td>
</tr>
</tbody>
</table>

Cherubini et al, Increasing enrolment in Clinical Trials and the PREDICT Study (www.predict.eu.org),
• Ways to improve:
  • Enrollment and Adherence
    • Initial communication with trusted professionals,
    • Emphasise benefits of participation to others
    • Detect potential signs of drop-out
    • Reiterate motivations
    • Enlist support from relatives, friends, physician and healthcare professionals
  • Home assessment visits
  • Newsletter/Feedback on study

Cherubini et al, Increasing enrolment in Clinical Trials and the PREDICT Study (www.predict.eu.org),
In Conclusion

- No trend for improving participation of older patients in cancer clinical trials
- Barriers are extensively studied worldwide
- Very few interventions to improve older patients accrual
- Multiple locks at different steps → Complex/multi-faceted Interventions

It is time to move from cognitive research to intervention

Gretchen, J Clin Oncol, 2005
Thank you for your attention