

**Another expected  
effect  
of  
CRCs-initiated  
cooperative study**

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# INTRODUCTION

- Clinical Research Coordinators (CRCs) play a very important role in conducting clinical trials. CRCs' routine work is to maintain the quality of clinical trials as a supporter of investigators.
- The number of CRCs has increased remarkably since the regulatory implementation of the International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines, and the role and necessity of CRCs in Japan has gradually become understood.

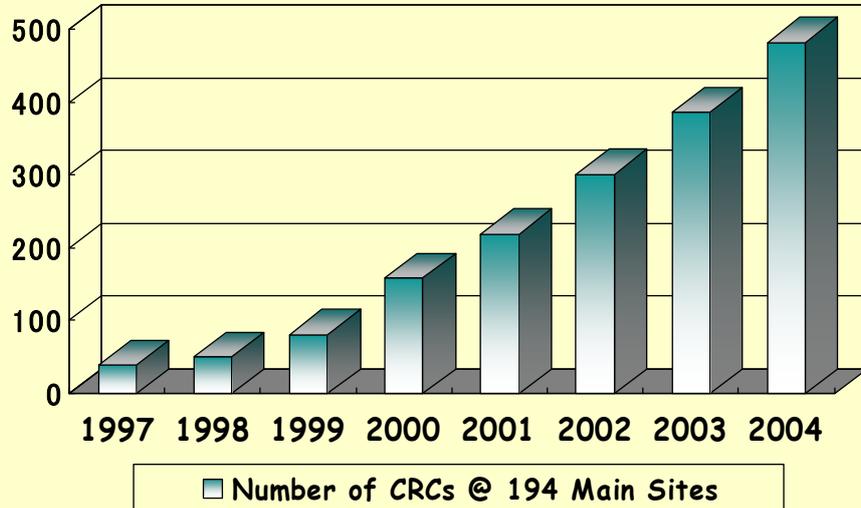
- The trainings for newcomer-CRCs are performed by the federal government ministries and by professional organizations. But there are not many extension courses for advanced-CRCs to enrich their expertise.
- The Japan-SoCRA Chapter or Comprehensive Support Project for Oncological Research of Breast Cancer (CSPOR-BC) are some of very few organizations that hold the extension courses for advanced CRCs.

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- To improve CRCs' motivation more and to enrich expertise as clinical research professionals, we think it is useful that CRCs conduct the clinical research by themselves.
- Therefore, we planned "CRC-initiated research", and conducted whole through the process from planning the concept of the research to writing a treatise.
- On this poster, we are reporting this activities.

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## Numbers of CRCs @ institute



Based on the data by Japanese society of Hospital Pharmacist

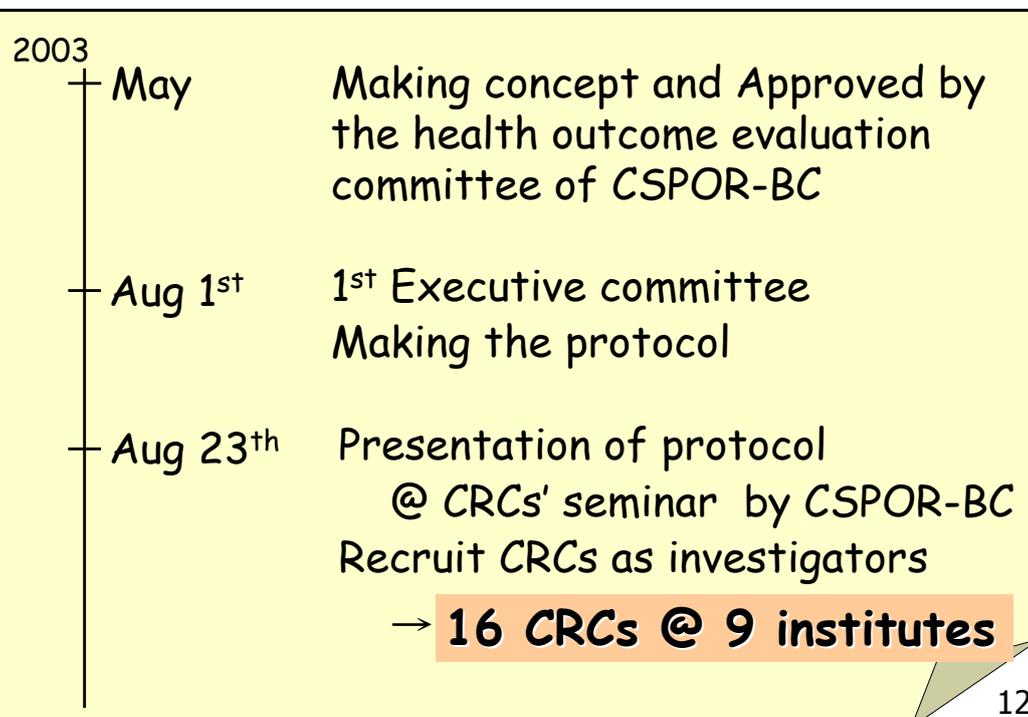
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**PROCESS**

## Executive committee

- 10 clinical research professionals
  - Detail
    - 5 of CRCs  
(over 5 years experienced)
    - 3 of Medical doctors  
(included 1 QOL specialist)
    - 2 of Bio-statisticians

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## Outlines of QOL survey

- Design
  - prospective survey
- Purpose
  - to investigate the relationship between the severity of anemia (Hb) and quality-of-life (QOL) of patients with cancer assessed by the Functional Assessment of Cancer Therapy (FACT)
  - Anemia

- **Sample size**

- 228

- **Participant**

- Oncology patients (mean age 59, range 27 to 84) who were under chemotherapy, hormone therapy, radiation therapy were followed for three months.

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- **Planned recruiting period**

- Oct 2003 ~ Nov 2004

- **Planned research period**

- Oct 2003 ~ Mar 2005

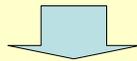
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# SCHEMA

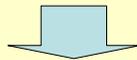
## Inclusion criteria

**The patients who were receiving or who were planning to have cancer treatments\*.**

\* chemotherapy, hormone therapy, and radiation  
exclude surgical treatment



**Informed consent**



**QOL questionnaire [FACT-An Version 4]  
Baseline & 3 months later**

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- Time for QOL questioner
  - 15min ~ 30min / 1 participant
- How to ask QOL questioner
  - Sometimes CRCs read out each questions for participants, and sometimes answered by themselves, depends on their condition

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# RECRUITING



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# Remark of CRCs

We could make team spirit !

We were motivated!

It worked good for other trials too after survey!

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# DISCUSSION

- It became possible to find aggressive CRCs, because we announced at the extension courses for CRCs of CSPOR-BC.
- So, it was easy to obtain the doctor's cooperation for the CRCs, because they had already built good relationship with them through their routine work. Therefore all process of the research from recruitment participants to completing case report forms was proceeded smoothly.

- It was very good education for participant CRCs to get to know the role of central, that CRCs conducts whole process from planning protocol to writing treatise, and also that CRCs visited data center and so on.

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## CONCLUSION

- The academic activities which CRCs initiate own research have an effect to proof hypothesis and also another effect which is to improve CRCs' motivation more and to enrich expertise as CRCs, and to play a part in improvement of the quality of the clinical trials.

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## Acknowledgement

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