

J-SUPPORT Policy No. 1 Basic Terms

ver. 3.3 November 15, 2022

1. Definitions

J-SUPPORT (Japan Supportive, Palliative and Psychosocial Oncology Group) is a multi-center clinical study group that implements and supports approved research in accordance with J-SUPPORT policy for research supported by public and private research funding.

Under the Executive Committee, J-SUPPORT is composed of the Research Group, which provides research support; the Monitoring and Management Department, consisting of the Scientific Advisory Committee, Independent Data Monitoring Committee (IDMC), Audit Committee, and Advisory Committees; and the Central Support Office, including the Data Science Team and Operations Office. J-SUPPORT is an unincorporated voluntary organization composed of J-SUPPORT Members (Fig. 1).

2. Objectives and Activity Goals

2.1 Objectives

J-SUPPORT aims to develop new treatments and verify standard treatments, verify support programs suited to the culture of and systems in Japan, conduct surveillance and clinical research on supportive care nationwide, conduct research activities to work toward the introduction and dissemination of standard supportive care based on scientific evidence, and establish supportive care in the field of oncology, which is inadequately addressed worldwide.

2.2 Activity Goals

J-SUPPORT activity goals strive to maintain and improve the lifestyle and Quality of Life (QOL) of cancer patients and their family, and develop systems that provide supportive care, through the following activities.

- 1) Provide accompanying support from the research planning and formulation stage
- 2) Provide the opportunity for networking and bridge-building mediation among researchers
- 3) Implement high-quality research
- 4) Provide research infrastructure to improve quality
- 5) Propose outcome indices, such as QOL scales
- 6) Promote the effective introduction and dissemination of supportive care
- 7) Ascertain the actual situation and propose new research topics.

3. Basic Philosophy and Policy

3.1 Basic Philosophy

All of the research activities conducted by J-SUPPORT comply with the basic principles of medical research set forth by the World Medical Association in the Declaration of Helsinki, the various ethical guidelines established by concerned ministries and government agencies, and applicable laws and regulations and guidelines, to ensure the ethical, scientific, and reliability standards of the research.

3.2 Basic policy

The basic policy for the operation of J-SUPPORT comprise the following.

- 1) All Japan
Mobilize all the available resources in Japan, while being unconstrained by existing organizations
- 2) Bridging and optimizing
Optimize small-scale research through bridge-building mediation at the concept stage
- 3) Cooperation
Cooperate with existing research groups, to lead to reliable outcomes without becoming mired in individual interests, and work hard for patients and their families throughout Japan
- 4) Dialogue and diversity
Hold repeated dialogue among stakeholders while respecting regional, group, institutional, and occupational differences, making the utmost effort to develop supportive care

Executive Committee members shall be the following people. Each member shall represent each of the positions and participate in deliberations in the Executive Committee.

- 1) Chair of each committee
- 2) Operations office
- 3) Chief Director of each research group
- 4) J-SUPPORT Members nominated by the Executive Committee chair

4.3.4 Executive Committee Secretariat

The Executive Committee Secretariat conducts administrative work, such as organizing Executive Committee meetings and reviews. The Executive Committee Secretary General shall be the Executive Secretary General.

4.3.5 Term of Office of Executive Committee Members

The term of office shall be three (3) years, and the members may be reappointed. When a member is appointed partway through a term of office, the term of office shall be the remaining term.

4.4 Monitoring and Management Department

The J-SUPPORT Chair shall establish Advisory Committees responsible for conducting activities as the Monitoring and Management Department for J-SUPPORT research and organizational management, and shall appoint one chair for each committee. Each committee chair shall appoint the members for each committee. The nominated members are appointed by the J-SUPPORT Chair after deliberation by the Executive Committee. The responsibilities of each committee are as follows.

4.4.1 Scientific Advisory Committee

The Scientific Advisory Committee invites outside experts to the Scientific Advisory Meeting when necessary, conducts peer reviews and examines protocol concepts, and reports the evaluation results to the Executive Committee.

4.4.2 Independent Data Monitoring Committee

The IDMC monitors each J-SUPPORT clinical study and reviews the continuation of each study based on reports on the study progress, efficacy, and safety. When necessary, it recommends discontinuation of a J-SUPPORT study or revision of the protocol. Three or more people are assigned to one study; members assigned to each study are members not directly involved in the clinical trial in question, and includes at least one member of the J-SUPPORT Executive Committee. The members are appointed by the Chair of the IDMC.

4.4.3 Audit Committee

Audits of participating institutions are conducted as necessary, with the aim of improving quality to ensure the reliability of J-SUPPORT research results. The Audit Committee Chair may outsource the work to a third-party organization if required to ensure impartiality.

4.4.4 Education and Training Committee

The Education and Training Committee plans and implements various education programs for researchers, data managers, executive secretariat staff, and the public, with the aim of improving the quality of J-SUPPORT research.

4.4.5 Translational Research Committee

The Translational Research Committee provides support to the development of sample analysis systems and to researchers conducting sample analyses in J-SUPPORT research.

4.4.6 Regulatory Affairs Committee

The Regulatory Affairs Committee collects information on pharmaceutical regulation and insurance administration and regulatory requirements pertaining to developing infrastructure for clinical research implementation systems. It makes proposals for projects that J-SUPPORT should be involved in.

4.4.7 Development Strategy/Research Seeds Selection

This committee confirms an overview of the progress of research in Japan and creates and proposes a development strategy map.

4.4.8 Research Policy Committee

The Research Policy Committee creates and publishes “Research Policies in the Field of Supportive and Palliative Care,” which are indispensable for the promotion of clinical research in the field of supportive and palliative care and the development of new treatments.

4.4.9 Patient and Public Involvement Committee

Patient and public involvement is indispensable, as it significantly contributes to establishing a framework for the development of supportive care. This committee considers mechanisms with patient

representatives, public representatives, and others, and conducts activities to proactively promote this involvement.

4.4.10 Negotiation Committee

The Negotiation Committee actively works and proposes solutions in cases when it is necessary to coordinate with other research groups when carrying out research.

4.4.11 Ad hoc Committee

Ad hoc Committees are established temporarily by the J-SUPPORT Chair when it is necessary to deal with matters that cannot be handled by existing committees.

4.4.12 Terms of office of each committee chair and committee members

The term of office shall be three (3) years, and the chair/members may be reappointed. When a chair/member is appointed partway through a term of office, the term of office shall be the remaining term.

4.5 Research Support

4.5.1 Names of research groups

The following research groups are established within J-SUPPORT.

Research groups
Supportive and Palliative Care
Psychosocial and Survivorship Care

(As of July 1, 2022)

4.5.2 Chief Director

The J-SUPPORT Chair shall appoint the Chief Director after deliberation by the Executive Committee. The term of office of the Chief Director shall be three (3) years, and the Chief Director may be reappointed. When a Chief Director is appointed partway through a term of office, the term of office shall be the remaining term.

The Chief Director shall build mentorship by coordinating between mentors and inexperienced researchers, and shall endeavor to provide accompanying-type support from the early stage of research. Mentorships shall be approved by the J-SUPPORT Chair after deliberation by the Executive Committee.

4.5.3 Director

The director shall be responsible for research consultation and shall support concept creation. The director shall also attend the Executive Committee meeting once a month and report on progress.

4.5.4 Mentor

Mentors provide accompanying-type support by participating as joint researchers in research conducted by inexperienced researchers, to assist in the process from formulating the plan through to completion, and to maximize the social impact of the research results.

Mentors are recommended by the Chief Director and appointed by the J-SUPPORT Chair.

4.5.5 Establishment, integration, and abolishment of research groups

1) Establishment

When establishing a new research group, the person intending to chair the research group submits an application to the Executive Committee, and the application is approved by the J-SUPPORT Chair after deliberation by the Executive Committee.

2) Integration, abolishment

When a research group is to be integrated with another group or abolished, the respective Chief Director submits an application to the Executive Committee, and the application is approved by the J-SUPPORT Chair after deliberation by the Executive Committee.

4.6 Central Support Office

4.6.1 Operations Office

The operations office is responsible for the administrative work of the Executive Committee. This office provides support to the research chairs and research offices regarding study design, protocol creation, data center selection, and conference/paper presentation, to maintain the quality of J-SUPPORT research and ensure the research is implemented without delay. The J-SUPPORT Chair appoints one Operations Office chair as the manager of the operations office. The Operations Office chair nominates an officer for the operations office. The nominated officer is appointed by the J-SUPPORT Chair after deliberation by the Executive Committee.

4.6.2 Data Science Team

The Data Science Team coordinates the implementation system for clinical data management and statistical analysis of J-SUPPORT research. It implements and supports clinical data management and statistical analysis and manages the Electronic Data Capture system.

4.6.3 Stakeholder Coordination Center

The Stakeholder Coordination Center gathers opinions from various stakeholders involved in the care of cancer patients (patient advisory, clinical advisory, national-level stakeholders), occasionally conducts small to large-scale surveys, and extracts evidence-based priorities.

4.7 J-SUPPORT Members

Researchers involved in cancer supportive care research that aligns with the purpose and activity goals of J-SUPPORT, who apply for membership using the prescribed forms, and have been approved by the J-SUPPORT Chair after deliberation by the Executive Committee, are referred to as J-SUPPORT Members (or simply “members”). Members consent to the operations office managing the list of member names and using the registration information for the purpose of information exchange and network building.

5. J-SUPPORT Research

Research that is reviewed and approved with the support of J-SUPPORT is collectively referred to as “J-SUPPORT research.” J-SUPPORT research representatives and principal investigators at participating facilities are limited to J-SUPPORT Members.

J-SUPPORT research is mainly classified into four types: J-SUPPORT New Research and Development, J-SUPPORT Interventional Study, J-SUPPORT Investigative/Observational Study, and J-SUPPORT Methodological Research. For joint research with a company or another research group, or consignment research, various matters, such as the research period and secondary use of data, are considered by the Executive Committee on a case basis (see Policy No. 2 Detailed Regulations for Research).

5.1 J-SUPPORT New Research and Development

Research and development of new drugs and devices at the exploratory stage of research, where the protocol concept has been reviewed by the Scientific Advisory Committee and approved by the Executive Committee, is defined as J-SUPPORT New Research and Development.

5.2 J-SUPPORT Interventional Study

Clinical studies implemented for the purpose of verifying the effects of new supportive care, palliative care, and psychosocial/behavioral intervention, where the protocol concept has been reviewed by the Scientific Advisory Committee and approved by the Executive Committee, are defined as J-SUPPORT Interventional Studies.

5.3 J-SUPPORT Investigative/Observational Study

Studies conducted with the aim of ascertaining needs and establishing concepts that contribute to the development of new supportive care, standardizing developed interventional techniques, examining the effect at a regional population level, and monitoring the introduced/disseminated results on clinical practice, where the protocol concept has been reviewed by the Scientific Advisory Committee and approved by the Executive Committee, are defined as J-SUPPORT Investigative/Observational Studies.

5.4 J-SUPPORT Methodological Research

Research that examines the methodology of research conducted and supported by J-SUPPORT, where the protocol concept has been reviewed by the Scientific Advisory Committee and approved by the Executive Committee, is defined as J-SUPPORT Methodological Research.

5.5 Research period

The research period in J-SUPPORT shall be the period from the day the research is approved as J-SUPPORT research by the Executive Committee until the day the main paper is accepted and the summary report is submitted to the Executive Committee.

5.6 J-SUPPORT Research Number

J-SUPPORT research is allocated a J-SUPPORT research number by the J-SUPPORT operations office on the day the research is approved by the Executive Committee. The following figure shows an example of an allocated J-SUPPORT research number.



Figure 2. J-SUPPORT research number allocation example

6. **Bylaw provisions**

Bylaws required for the enforcement of J-SUPPORT Policy No. 1 Basic Terms may be established by the J-SUPPORT Chair after deliberation by the Executive Committee.

7. **Revision of J-SUPPORT Policy No. 1 Basic Terms**

J-SUPPORT Policy No. 1 Basic Terms may be revised with the approval of the Executive Committee. Approval shall, in principle, be based on consensus, with the unanimous approval of all members of the Executive Committee. If unanimous approval is not obtained, the revision may be approved by majority consensus of the Executive Committee members, at the discretion of the J-SUPPORT Chair (Executive Committee chair).

Minor revisions may be approved at the discretion of the chair of the J-SUPPORT operations office.

Supplementary provisions

1. These terms shall take effect from February 19, 2016.
2. The names and affiliations of the constituent members upon establishment of this voluntary organization are as follows.
 - Name: Yosuke Uchitomi (National Cancer Center)
 - Name: Tsutomu Suzuki (Hoshi University)
 - Name: Akira Ueno (Tohoku University Graduate School)
 - Name: Daisuke Fujisawa (Keio University)
 - Name: Takuhiro Yamaguchi (Tohoku University Graduate School)
 - Name: Yoshiyuki Kizawa (Kobe University Graduate School)
 - Name: Yasuhito Uezono (National Cancer Center)
 - Name: Sadamoto Zenda (National Cancer Center)
 - Name: Eriko Satomi (National Cancer Center)
 - Name: Yutaka Matsuoka (National Cancer Center)
 - Name: Ken Shimizu (National Cancer Center)
 - Name: Masashi Kato (National Cancer Center)
 - Name: Narikazu Boku (National Cancer Center)
 - Name: Tatsuo Akechi (Nagoya City University Graduate School)
 - Name: Tatsuya Morita (Seirei Mikatahara General Hospital)
 - Name: Mitsunori Miyashita (Tohoku University Graduate School)
3. At the time this voluntary organization was established, Yosuke Uchitomi was the J-SUPPORT Chair and Executive Committee Chair. The Executive Committee members were Tsutomu Suzuki, Akira Ueno, Daisuke Fujisawa, Takuhiro Yamaguchi, Yoshiyuki Kizawa, Yasuhito Uezono, Sadamoto Zenda, Eriko Satomi, Yutaka Matsuoka, Ken Shimizu, Masashi Kato, Narikazu Boku, Tatsuo Akechi, Tatsuya Morita, and Mitsunori Miyashita.
4. The term of office of the Executive Committee Chair and members at establishment was until March 31, 2018.
5. The Operations office of this volunteer organization is located in the National Cancer Center.
6. The Placebo Ad hoc Committee was established on October 14, 2016.
7. Terms ver. 2.0 came into effect from April 1, 2020.
8. J-SUPPORT Terms came into effect as J-SUPPORT Policy No. 1 Basic Terms ver. 3.2 on August 19, 2022.
9. J-SUPPORT Policy No. 1 Basic Terms ver. 3.3 came into effect on November 15, 2022.