Chapter 19. Ethical, legal and societal issues of research and innovation in NESTORE

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Abstract: Ageing population is growing faster in the European Union. Information and Communication Technologies can provide solutions for Active Ageing. NESTORE will develop an innovative, multi-dimensional, personalized coaching system to support healthy ageing by generating and sustaining motivation to take care of health and by suggesting healthy nutrition and personalized physical and mental coach, as well as social interaction, to prevent decline and preserve wellbeing. The chapter analyses the ethical, legal and societal issues (ELSi) of the research and innovation processes in NESTORE project. First, the work will study some of the prominent ethical issues posed by NESTORE and how to assure autonomy and informed consent. Second the work focuses on the personal data treatments and how to assure privacy and confidentiality according to the General Data Protection Regulation. Finally, it includes the Responsible Research and Innovation approach for this particular project. The main goal is to provide practical information on how to implement the NESTORE ELSi that could be useful for future projects based on convergence of technologies and data driven oriented to foster research and innovation in ageing and wellbeing.

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1. Introduction

One of the most important challenges that western societies must tackle is ageing. The increase in life expectancy results in the rise of a population with physical and psychological dependencies and with multiple ailments. In our society, which idolizes consumption and youth, there's a lack of awareness about the situation of elderly people and frequently it seems to be a taboo subject. NESTORE is a multidisciplinary, European Union funded consortium aiming to develop an innovative, multi-dimensional, personalized coaching system to support healthy ageing by generating and sustaining motivation to take care of one's own health; and suggesting personalized nutritional and physical advice in the form of a digital coach, as well as boosting social interaction, preventing decline and preserving wellbeing.

This project is designed to use personal data to improve decision-making in real-life settings. Personal data are the gold of our time, and health, biometric and socio-demographic data are special categories of data[1] that require the highest protection because they say everything about us; and because they could be used for unwanted purposes and give rise to covert discrimination, with profound implications for people's freedom and that of future generations. The possession of personal datasets by third parties, whether private or public initiatives, could affect our rights depending on the uses, giving these third parties extraordinary power over us. The decisions taken in the field of health research and innovation and in highly digitized contexts will mark the lives of people, groups and societies.

Since the beginning of this century, Europe has been committed to a data-driven society. It is a political and economic decision, which also includes knowledge creation and transfer processes. The goal is a single and competitive digital market, capable of guaranteeing the protection of people's rights and freedoms and promoting research and innovation based on the intensive exploitation of datasets, including personal data[2]. In the field of healthcare this commitment results in more personalized medicine, more efficient health care systems, the prediction of the adverse effects of drugs with a smaller number of people exposed to risk, active ageing and well-being; and pandemic prediction and management systems. All these areas, in which many substantial public and private research and

[1] Personal data are any information relative to a living, identified or identifiable individual. The separate information, which complied could lead to the identification of a particular person, is also classed as personal data. Examples of personal data: name and surname, address, email address of the kind name.surname@company.com, national identity number, location data (such as a mobile telephone's data location function), Internet Protocol (IP) address, a cookie identifier, the telephone's advertising identifier, the data in the possession of a hospital or doctor, which could be a symbol to uniquely identify a person. See European Union "What are Personal Data?" https://ec.europa.eu/info/law/law-topic/data-protection/reform/what-personal-data_es

[2] European Digital Single Market: https://ec.europa.eu/digital-single-market/en/news/digitalyou-digital-trust

innovation consortia are funded, based on the said technologies and on the development of mHealth, are underlain by the exploitation of datasets, including personal data, and for which the participation of third parties traditionally outside the field of biomedicine and healthcare is necessary. These third parties, who may be either private companies or even public authorities, are interested in accessing different personal datasets, for what they may say about their owners and for what they could predict, an interest that may be different from, and even contrary to, that of the research project leaders.

In the digital society we have ceased to be anonymous and have become re-identifiable. Our gender, postcode and date of birth identify us with a very high percentage of success[3]. Due to the development of technology and the huge amount of personal information amassed in different databases, and to the data we disclose, it is possible to create patterns of behaviour, predict conducts and, therefore, improve decision-making. For that it is necessary to programme algorithms that are fed by datasets including personal data. These personal data, as the main raw material, are the property of their owners, who in turn will be the final targets of the results of the research and innovation processes with the special situation of health data.

The current review model – born and raised in the second half of the 20th century – for analysing research projects in which humans take part and/or their data personal is used, is outdated and ineffective, due to the technical, ethical and legal challenges posed by personal data processing in the 21st century. Nowadays the analysis of the ethical, social and legal issues must focus on protecting people by safeguarding their personal data and ensuring their owners' privacy and confidentiality. The exercise of autonomy to make free and informed decisions must be promoted and guaranteed to avoid discrimination (specifically when it is covert) with fairness and transparency. There has to be a balance between maximizing the benefits and minimizing the risks also includes processing personal data properly. We are facing a new paradigm in research and innovation based on data driven interventions where providers of data are final users and participants of research. This new digital approach were data and datasets are fuelling almost all activities of our lives, pose challenging situations and questions that should be solved, and it is an evolving situation full of grey areas in data protection in research.

The main objective of this chapter is to integrate the ethical, legal and societal issues of the NESTORE project, including international guidelines such as the General Data Protection Regulation and Responsible Research and Innovation aspects. The aim of this analysis, and of the project at large, is to ensure that the rights and freedoms of the subjects involved are guaranteed, including the protection of personal data -and those involving what are considered special categories-, and additionally, to ensure freedom of research. NESTORE aspires to use its results to improve the quality of life of the elderly and promote active ageing and wellbeing with the help of the best technology possible, while respecting and promoting freedoms and human rights of the subjects involved.

2. Autonomy, information and informed consent

One of the key innovation elements in NESTORE is the design of "pathways of interest" able to provide hints and services according to the user's preferences, while ensuring that the overall wellbeing and

[3] Sweeney, L., "Simple Demographics Often Identify People Uniquely". Carneggie Mellon University, Data, Privacy Working Paper 3. Pittsburgh 2000. Available at: https://dataprivacylab.org/projects/identifiability/paper1.pdf

health status is maximised. NESTORE leverages on the following novel Information and Communication Technologies:

1) multi-domain unobtrusive monitoring system, including wearable and environmental sensors and tangible objects

2) an intelligent Decision Support System, to analyse the participants behaviour and provide personalized targets toward wellbeing

3) active coaching, developed as a conversational agent, embodied in a physical companion that assumes different forms, able to establish affective communication through multimodal communication channels and to engage older people with personalized coaching activities in a single or multiple domain[4]

These interventions pose challenges to the participants and responsible of the study regarding autonomy, privacy and ethical issues that must be analysed.

Any potential research participants must understand that their participation in any given study does not always imply a direct benefit to their health or specific condition. Furthermore, they should be aware that their contribution could be for improving scientific knowledge only. The process of informing research participants should begin with a general description that should be very brief, with relevant information expressed in clear and understandable terms according to the potential participants.

Information provided to participants should inform about the purpose of the project to be an innovative, multi-dimensional, cross-disciplinary and personalized coaching system. In our case with the NESTORE project, it should be ensured that research participants would receive adequate information and the proper explanations to understand that the NESTORE system is like a virtual friend, a companion and a coach. Importantly, in case of incidental findings, participants should first know what these are and that they are will be immediately informed if researchers detect any sign during the evaluations or system use period that could indicate a potential health problem that requires a medical follow-up. Participants will receive an alert to seek the proper care and attention from the appropriate healthcare services.

Participants of any research project should be informed about the type of data, including personal data of special categories of nature, and receive a clear explanation regarding its use, implications for privacy and other rights implied and the specific purpose of the treatments proposed. A key issue of the information process and informed consent procedure is to inform subjects about data protection measures to assure respect for privacy and confidentiality and any kind of potential or real discrimination of the research subject by misuses of data.

Regarding economic compensations, research participants should be informed that their participation in the study will not cause any economic burden for them and should be aware of the conditions established for travel expenses, dietary expenses or reimbursements. It is important to note that any economic compensations should not be established to a limit that would affect or modify the free will of participants to the extent of coercion or undue influence to participate. While research should always avoid conflict of interest, if any does exist, researchers should declare it clearly and

[4] See Cordis NESTORE https://cordis.europa.eu/project/id/769643/it

transparently and participants should be aware. Participants and members of society should understand that there are different types of conflict of interests, not only economic, but also of a personal natural, hierarchical, etc. At any time, researchers should check and avoid misconceptions of participants regarding the specific intervention proposed.

The verbal and written process of information should be accompanied by an informed consent template covering all these aspects to be signed by research participants, where they can decide whether to comply with the proposed research. The specific template should include again, general information about the project (title, reference, funding, principal investigator, etc.) and the name and surnames of the potential participant. As a general guide, this informed consent template should clearly state that participants:

1) have read the information template given to them about the research study after being informed of the abovementioned issues;

2) can ask questions about the study;

3) have received enough information about the study;

4) have spoken with the researchers involved in the project;

5) understood that their participation is voluntary and that they can withdraw from the study at any time and without giving any explanation and without this having an impact on their situation (medical care, etc.)

In order to promote autonomy and according to the general rules and requirements information and informed consent procedures, all research interventions, including those like NESTORE, should provide the following information:

- title of the study;
- clear information regarding who is in charge of the research and funding (adding references if necessary) and the identification of the main researchers.
- This information should be followed by a brief introduction in order to inform participants about the proposed research to decide whether participate.
- In the same process of information and informed consent templates, participants should be aware that the research has been approved and reviewed by the entitled research ethics committee of the research centre involved.
- Specific information should be provided about the ethical and legal framework applicable, integrating international, European, national and local guidelines and regulations depending on the type of research and paths to follow.
- Give potential participants names, phone numbers and contact addresses of the main researchers to contact them at any time and to make them understand that they can ask any questions.

- Likewise, they are free to be part or to revoke consent at any time without any explanations and with no negative consequences i.e., In receiving treatments, if this is the case, etc.)

The final goal is to provide to potential participants with all elements they may need to make a rational decision and assure that their consent is free and voluntary. Information on informed consent is part of a process that includes verbal communication and written information and that obliges those responsible for research to provide any information that the participants should need at any time.

3. Personal Data Protection in digital environments

In May of 2018, The General Data Protection Regulation[5] introduced new requirements to assure that privacy and confidentiality will be protected through data treatments. The General Data Protection Regulation has established specific principles, rights, obligations, guarantees and institutions such as the Data Protection Officer as an independent advisor on data protection. The key point is to assure that data owners have the control over their personal information and how it is treated by controllers and processors

For treatments in research of personal data of special categories, i.e., health care data, which is the case in the NESTORE project, the General Data Protection Regulation establishes not only specific guarantees, but also specific security measures that the NESTORE project has carefully analysed and followed.

The main questions to be answered for European Research Projects such as NESTORE regarding data treatments including personal data and partners involved are:

1) Is the information and informed consent process of participants developed according to the General Data Protection Regulation?

2) Will the data be anonymised, codified or pseudonymised in the framework of the research process?

3) Where are the data (main researcher´s institution, format, database, etc.)?

4) Will the data to be sent or shared between partners?

5) Will cloud services be deployed to store data and conditions?

6) Will the project require the services of third parties for data treatments and what will be the possible implications of this for participants/data owners?

7) Will the data to be sent/transferred outside of the European Union?

[5] Regulation (UE) 2016/679 of the European Parliament and the Council, of 27 April 2016, relative to the protection of individuals with regard to the processing of personal data and the free circulation of these data, repealing Directive 95/46/EC (General Data Protection Regulation) (Text relevant for the purposes of the EEE) https://eur-lex.europa.eu/legal-content/ES/TXT/?uri=CELEX:32016R0679

To give a practical example, the following steps will be taken to assure data protection in the NESTORE project, which is based on datasets that include personal data and special categories of data:

1) All partners involved should be clearly identified and those responsible for data treatments should be determined too, due to co-responsibility (art. 26 General Data Protection Regulation). As stated before, the principle of minimisation of data, is an obligation of the NESTORE team to determine if the data that are going to be treated are adequate, pertinent and proportionate to the purpose determined.

2) All procedures for personal data collection should be identified and this information will then be crucial to build the information and informed consent process accordingly (interviews, records, tracking, monitoring, etc.), as described above. At this point all technological solutions for storage should be analysed (cloud, servers, networks, etc.) and the measures to guarantee data protection that should be deployed should be determined.

3) Consequently, transfers of data, if any, should be identified. If there will be third parties in charge of data treatments, the contracts should be built and reviewed accordingly. International data transfers, if any, should be determined too. For this reason, it should be checked if there is a specific informed consent of the entitled person for the transfer process; the Privacy Shield or the Authorisation of Data Protection Authorities (art. 45 to 49 General Data Protection Regulation).

4) In the case of the NESTORE project, due to the results of the previous analysis and because of the potential high-level impact of the NESTORE interventions in the rights and freedoms of potential participants, the next step is to undergo a Data Protection Impact Assessment (DIPA).

All participants in research, and members of projects such as NESTORE, should understand the meaning of personal data in the digital society. As defined in the General Data Protection Regulation, Personal data means information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (art. 2(a) General Data Protection Regulation).

The General Data Protection Regulation establishes the obligation to carry out a Data Protection Impact Assessment in research projects based on personal data treatments, in particular when using special categories of data with the aim of analysing in depth and minimizing the human rights and liberties risks of individuals involved. A Data Protection Impact Assessment must: describe the nature, scope and purposes of the processing; assess necessity, proportionality and compliance measures; identify and assess risks to individuals and identify any additional measures to mitigate those risks. From the DPIA an action plan will result that must be carried out to mitigate the risks detected and which will have to be reviewed periodically and updated in the event of possible changes in data processing. It is important that this review not be thought of as a mere formality, but as a living process that may be subject to change and which makes it possible to properly monitor the project and the guarantees to be applied for personal data protection. The Data Protection Officer is the independent figure advising on these procedures.

The goal of adequate data protection protocols is to prevent participants from being identified, understanding that the main researchers and those granted specific permission and access would, if necessary and justified, connect personal data of participants with i.e., medical records. Only the entitled authorities (i.e., healthcare), and Research Ethics Committees involved and staff involved in the study, will have access, for the purpose of making sure data and procedures of the research, this is compatible with protecting confidentiality at all times. Transfers of participant´s personal data between partners and third parties should be determined and explained to those affected from the beginning of the project and data transfer agreements must be signed. This should only involve encrypted data, which in no case will contain information that can identify the participant directly (such as name and surnames, initials, address, social security number, etc.). It must be said that any staff in contact with personal data should apply the highest standards of protection of privacy stated in deontological, ethical and legal regulations.

Additionally, participants should be informed that according to the General Data Protection Regulation they can also limit the processing of incorrect data, request a copy or transfer of the data provided to the study to a third party (portability). To exercise these rights, or if participants would like to know more about confidentiality, they can contact the principal investigator of the study and the entitled Data Protection Officer through the specific email assigned (each institution should add a specific address). Furthermore, participants should be informed that if they decide to leave the study, no new data will be collected, but data generated for research purposes until that time cannot be destroyed. Participants should be informed about the obligations of the responsible of the treatments to keep the data collected for the study and indicate for how long after its completion.

4. Ethics and research integrity

For all activities funded by the European Union, ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence[6]. Research, including its outcomes and the way it is conducted, should be morally grounded and acceptable to society. [7]Honesty, accountability, fairness and good stewardship should be core principles of research and innovation. Scientific integrity is a core issue for the NESTORE project. It applies to the public and the private initiative that should be working together to become a digital, data driven society where research and innovation are core elements[8].

There is not a scientific integrity definition shared by the scientific community. Censurable behaviours can be found in all research areas: in supervision, statistics data uses, or in publishing and plagiarism. The causes of censurable behaviours are separated into individual, organizational –among which there is the lack of institutional policies that are ethically solid and fair- and structural ones, like the pressure to get good results and funds to support researches or appearance of new areas with an undeniable

[6] COM. (2001). European Governance - A White Paper. Brussels.
[7] Engage2020. (2015). Science, Society and Engagement- An e-anthology. (E. Andersson, S. Bussu, & H. Davis, Eds.).
[8] Casado, M. et al., *Declaration on scientific integrity in Responsible Research and Innovation*, Universitat de Barcelona Editions, 2016 Available at: http://www.publicacions.ub.edu/refs/observatoriBioEticaDret/documents/08489.pdf

therapeutically potential that create economic, social and media interest, for which there is available finance, more competitiveness.

Considering the great cultural, social and economic differences it can be difficult to draw up one set of guidelines that will apply to every country. Therefore, The Declaration of Helsinki[9] of the World medical Association or the Council for International Organizations of Medical Sciences International ethical guidelines for health-related research involving humans[10] have long been held as a reference standard of ethical practice guidelines for the scientific community.

These international codes of conduct can act as templates to be followed by each country to draft their own code of conduct, with rules and policies specific to their national structure and systems, that will identify with both their workforce and citizens. In the European context, the All European Academies, a consortium of 50 academies from almost all EU member states, has done this with their European Code of Conduct for Research Integrity[11]. It serves as a framework of self-regulation for the European research community. The Code states four core principles of good research practice: reliability, honesty, respect and accountability, and gives recommendations on how to respond adequately to violations of these principles.

The Singapore Statement on Research Integrity[12]states that it is "intended to challenge governments, organizations and researchers to develop more comprehensive standards, codes and policies to promote research integrity both locally and on a global basis". Like the previous code, the Singapore Statement also lays out four basic principles for research integrity: Honesty, accountability, professional courtesy and fairness and good stewardship. While the two documents differ slightly in their chosen principles, the overall idea is the same: responsible research, with a solid foundation of integrity and ethical principles, is vital to all disciplines, worldwide, and will increase the validity of results and the public trust.

5. Responsible Research and Innovation

Responsible Research and Innovation is a dynamic, iterative process in which all stakeholders become mutually responsive and share responsibility for both the process and its outcomes. In this framework, scientific inquiry is a process not limited to the perspective of the researchers. Societal actors such as citizens, policymakers, business or third sector organizations can and should be involved during the whole research and innovation process. The objective of RRI is to create high-quality science aligned with the values, needs, and expectations of society[13]. Implementing Responsible Research and Innovation leads to a more engaged public, responsible actors, and responsible institutions. It also has

[9] *WMA*, Declaration of Helsinki https://www.wma.net/es/que-hacemos/etica-medica/declaracion-de-helsinki/
[10] CIOMS- *Guidelines for Health-related Research Involving Humans*. Available at: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
[11] ALLEA – All European Academies, *The European Code of Conduct for Research Integrity*, Berlin 2017, Available at: https://allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf
[12] Resnik, D. B., & Shamoo, A. E. *The Singapore statement on research integrity. Accountability in research,* 18(2), 71–75, 2011. https://doi.org/10.1080/08989621.2011.557296
[13] Gerber, A., Forsberg, E. M., Shelley-Egan, C., Arias, R., Daimer, S., Dalton, G., Steinhaus, N. *Joint declaration on mainstreaming RRI across Horizon Europe.* Journal of Responsible Innovation. Routledge.2020 https://doi.org/10.1080/23299460.2020.1764837

benefits for research and innovation, as Responsible Research and Innovation strives for making science and technology more ethical, sustainable and socially beneficial.

Ethics, public engagement, gender equality, open access and scientific education are the transversal agendas of Responsible Research and Innovation in HORIZON2020 European Research Program and an essential part of NESTORE from the inception of the project and throughout its lifecycle. Societal expectations of the elderly are crucial to move the project forward and should be aligned with research and innovation processes. That means considering gender equality goals, to promote with the NESTORE coach ageing and wellbeing responding to the needs of women too. In this sense it is a fact that women live longer and are capable of being more independent. In particular, the NESTORE project has specific goals regarding dissemination activities, and up to now has been very active in delivering information through its website[14] related to ethical, legal, societal and even technical issues on ageing and wellbeing in this digital society.

NESTORE is a multidisciplinary project that has been deployed and developed following the principles and human rights of the UNESCO Declaration on Bioethics and Human Rights (2005)[15], The Council of Europe Convention on Biomedicine and Human Rights (1997)[16] and in particular will consider all legal and ethical requirements at European, international and national level and global approach. For all activities funded by the European Union, ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence. Research, including its outcomes and the way it is conducted, should be morally grounded and acceptable to society. [17]Honesty, accountability, fairness and good stewardship should be core principles of research and innovation.

Ethics in Responsible Research and Innovation relates to three main areas, ethical research, research integrity, and societal acceptability. Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research. Research integrity means that research methods, activities, and processes are guided by standards, guidelines, and protocols; open to external scrutiny (for example, ethical bodies extended to societal stakeholders); and open to internal reflexivity (nurtured by a culture of open deliberative integrity). Social acceptability includes the consideration of the short-term and long-term implications of the research, and this should respond to actual social needs and reflect the basic values of society.

Data Management issues and in particular the principles "Findable, Accessible, Interoperable and Reusable" and are in close relation with the open access agenda and above all, scientific education - including digital literacy- is one of main goal. The objective is to empower the elderly and those individuals related to them (caregivers) in the use of new devices and technology. Likewise, the aim is to help them to have a better quality of life and reduce the burden of the health care system. Members of the NESTORE project have been proactive in coordinating and participating in activities of dissemination and knowledge transfer to promote public engagement. NESTORE research project should promote equal opportunities between men and women and aiming, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level. NESTORE partners from *Fundació Salut i Envelliment* have developed a checklist to assess gender view to the experts and

[14] See https://nestore-coach.eu/ethics.

technologists. This checklist could be used before or after the development of material, recommendations or feedback addressed to end-users. The goal of this tool was to help to achieve a gender perspective in NESTORE project to be more aligned with H2020 program and their gender perspective.

The NESTORE partners also reflect this attention to gender equality, by encouraging and supervising measures for the promotion of gender equality within the consortium Age-related and gender-related physiological differences among individuals were also considered on the definition of the parameters required to characterize the functional status of healthy elderly people and to follow their variations over time. At the Co-Design process, the gender dimension was considered during the design of the NESTORE solution and its components, in order to meet their needs through a participatory approach. The recruitment focused on a good gender balance and diverse ethnic representation.

Responsible Research and Innovation implies that the stakeholders in collaborative research projects such as NESTORE (staff members, researchers, data processers, research participants, charities, etc.), work together to ensure that the outcomes of the research are relevant to and align with, the needs of society. Public engagement as one of the key agendas of RRI is especially present in the NESTORE project. To provide an example from the very beginning of the research project, the first research intervention of the project was based on a series of workshops that took place at Sheffield Hallam University (March 2018), where up to 80 people aged 50-70 participated. A specific methodology was applied, and participants were recruited and observed, recording their interventions in audio tapes.

To begin, participants were informed about the overall aim of the research. Secondly, participants were informed that the co-design research intervention is to build understanding of attitudes and factors of health in community-living older people between 55 and 70 years old to technology, which can play a key role in supporting the needs of the ageing population.

The workshops included the following elements, which can act as a general guide to other similar EU projects:

- A description of the research project and the aims of the workshop and how this relates to the wider research programme in which it is positioned, if applicable.

- A description of the activities that will be used within the workshops and individuals were invited to give written consent to take part.

The goal was to answer the following questions: What do you understand by the term technology?; Can you describe particular technological products that you find helpful/unhelpful; What are the factors that help/hinder your engagement/use of technology?; Are there particular design features that you find helpful?

Regarding the benefits, risks and expected outcomes, participants were informed that the workshops will enable people to share their expertise, think and talk about what makes life meaningful. Researchers should aim to create a safe environment where the participants feel comfortable to talk openly. Through activities and discussions, participants will generate ideas about how future technologies could act as a coach to offer advice to help them to engage in meaningful activities. This can be a very valuable opportunity for the participants to feel included and heard, and for the researchers also, as they may not

have considered some of the points raised by the participants. As this is a co-design process, the participants are acknowledged throughout the research and will have the opportunity to continue to engage, contribute and feedback to the project as active 'team members' throughout.