SPECIAL ARTICLE

Royal Australasian College of Surgeons

Collaboration is the new competition: developing sustainable international collaborative research delivered by a National Surgical Trainee Collaborative Group

Introduction

Collaboration is defined in the Oxford dictionary as 'the act of working with another person or group of people to create or produce something'.[1] In the evolution of surgical research, collaboration is the new competition. This has been accelerated by the growth of trainee-led surgical research collaboratives. Advantages of collaboration include the sharing of ideas and perspectives regarding study design and conduct, the merging of data to create larger datasets and adequate power, and the pooling and efficacious use of resources. This facilitates robust methodology and the ability to allow individuals of diverse backgrounds/experience levels to become involved with high-impact research, translating to true patient benefit.[2] This article explores lessons learned from the founding and development of the trainee-led Irish Surgical Research Collaborative (ISRC), to provide a blueprint for development of a sustainable collaborative research (CR) structure.

Trainee-led surgical collaboratives

A growing number of trainee-led collaboratives have proven their feasibility and potential to deliver high-quality output, transforming the surgical research landscape.[3–7] This was recently demonstrated on a global scale by the unprecedented successes of the GlobalSurg/CovidSurg groups.[7] Pioneered in the UK in 2009, trainee-led collaboratives have since emerged from many jurisdictions, with VERITAS and TASMAN prominent examples in Australasia.

Benefits of collaborative work to surgical trainees

An understanding of research and an ability to critically appraise evidence are key components for certification as a surgeon. 'Capabilities' or 'competencies' in research are stated as fundamental requirements by UK, Ireland and Australasian governing bodies.[8,9] Previous iterations of the UK/Ireland Intercollegiate Surgical Curriculum Programme (ISCP) stipulated a prescribed number of first-author peer-reviewed publications as certification requirements, fuelling a culture of small studies, of limited clinical relevance.[3,10] Similar concerns regarding perceived pressure to pursue 'low-impact' research have been voiced by Australasian trainees.[11] Following significant representation by trainee groups,[10] the ISCP General Surgery curriculum has been modified to encourage participation in CR.[8] We hope that the future will see recognition of CR within both entry and certification requirements across all surgical specialties.

The Irish Surgical Research Collaborative

In recognition of the tremendous potential demonstrated by trainee-led research collaboratives originating elsewhere, and the absence of a similar model in Ireland, The ISRC was formed in 2015 by a small group of surgical trainees. The intention of the ISRC was to create a formal group in which Irish trainees could learn fundamental research skills and contribute to large-scale studies. It was also hoped that a trainee-led platform could enhance collaboration and data sharing between institutions that may have traditionally 'competed' in the research sphere.

Creation of such an organization has been a journey, with lessons learned along the way. Alongside aforementioned advantages, CR poses challenges – defining contributor roles, intellectual property ownership, data sharing, accountability and conflicts of interest, and building infrastructure.[12,13] Additional complexities pertain to clinical CR, such as coordinating patient recruitment and ethical approval across multiple sites. We aim to share our experience and learnings from establishing the ISRC.

Setting up a collaborative

Key steps in establishing a collaborative are outlined in Figure 1. The key first step is to identify and engage enthusiastic and committed colleagues.[3,13] The ISRC began as an informal conversation between surgical trainees with a vision of uniting peers nationally in pursuit of high-quality research output. More formal discussions ensued, followed by meetings with senior consultants (attendings) in a mentorship capacity. This group of trainees formed the first core leadership group of the ISRC, and organized and led all meetings. This core group then actively engaged with consultants and mentors, other trainees and other potential stakeholders to foster growth of the collaborative.

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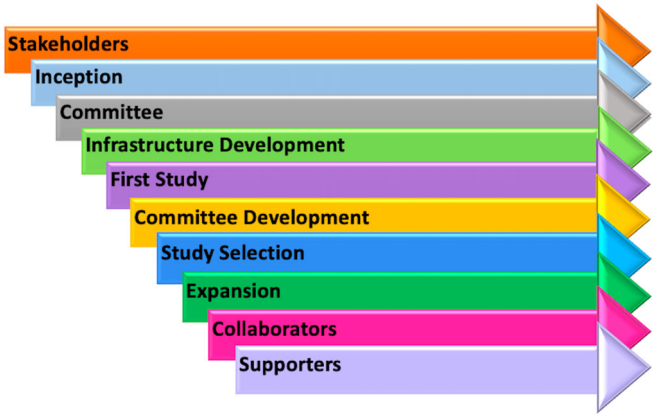

Fig. 1. Development stages of a research collaborative.

Committee structure

Committee structure may be inspired by that of existing organizations and tailored to fit the particular collaborative. At a minimum, we would suggest early establishment of chair, vice-chair and secretary. A treasurer and communications officer are also desirable. Clear designation of roles and responsibilities allows a collaborative to plan strategies. The need to recruit adequate personnel to deliver the work should be balanced against avoidance of burdensome layers of administration and dilution of individual engagement. We aimed for a task-focused model and stress the importance of recruiting a diverse skill-mix with representation across surgical specialties and grades as the collaborative grows (Appendix 1). For an equitable selection process congruent with diversity, we developed a transparent voting process across desirable domains for new members, and implemented an Annual General Meeting and constitution for governance.

Authorship

It is imperative to acknowledge the role of all collaborators in publication, and development of clear authorship criteria, with individual recognition proportionate to contribution, is essential. The ISRC adopted the National Research Collaborative and the Association of Surgeons in Training Collaborative Consensus group guidelines.[14] Roles and titles outlined are mapped to General Medical Council (UK) domains and International Committee of Medical Journal Editors criteria for the definition of authorship in academia. Utilization of this authorship recognition framework may be relevant for other training bodies internationally, for example, General Surgeons Australia.

Engagement with consultants

The collaborative model chosen by ISRC was entirely trainee-led and delivered, with consultants invited to act as advisors on a project-by-project basis. This allowed the collaborative to establish as an independent, self-motivated entity. It also allows the collaborative to maintain an identity as a broad group of cross-speciality trainees, avoiding 'ownership' or branding by a specific specialty or department, and allows invitation of experts based on the specific requirements of a project. All consultants approached have been supportive of the ISRC, readily offering expertise and advice and enrolling their patients in collaborative projects, for which they are recognized in authorship.

Engagement with trainees

A key lesson learned relates to engagement with individual units and trainees to promote involvement in projects. There are two strands to this: engaging members to be involved in study design, implementation and conduction, and engaging trainees to participate in local data collection. Engaging trainees on a local level requires clear communication about the work involved, and the associated reward or recognition. Additionally, ensuring user-friendly and secure infrastructure to facilitate trainee data collection and sharing is critical to maintain trainee engagement.

Engagement with existing infrastructure

It is important to consider how a developing collaborative will fit in with the existing local education and training infrastructure. Building a strong relationship with the Royal College of Surgeons Ireland (RCSI) was key in the progress of the collaborative. RCSI has supported the ISRC through assistance with administrative and database support, including the use of Research Electronic Data Capture (REDCap™), and by seeking trainee feedback on national research infrastructure, whilst allowing the ISRC to maintain independence. This formal link has facilitated increased research capabilities and allowed the needs of academically-inclined trainees be catered for in the national research framework.

Networking and developing links

A key element in the establishment of CR is surveying the wider landscape of collaborative work.

Other collaborative organizations

We found reaching out to individuals within other collaboratives, both for informal advice and to establish more formal collaborative links, crucial in accelerating our learning curve and growth. Combined projects between collaboratives can be an important way to increase recruitment and to develop an initial platform to launch wider projects. National and international 'umbrella' organizations linking research collaboratives, such as the UK National Research Collaborative (NRC),[15] are an invaluable means of identifying and forging links with like-minded organizations. In our case, being invited to participate in the NRC and subsequently to present a project proposal at the organization's national meeting allowed us to raise the profile of our first international project, to gain feedback and to benefit from peer mentorship.

Clinical trials units

Forming links with established clinical trials networks can maximize research impact. For example, the Birmingham clinical trials unit, and subsequently the Clinical Trials Network UK, have provided an important platform for the West Midlands Research Collaborative.[3] Similarly, in Australia and New Zealand, the Clinical Trials Network Australia and New Zealand (CTANZ) has supported and assisted trainee collaboratives.[16] Such relationships can be symbiotic. Trainee research collaboratives can also assist in the development of clinical trials networks, by providing drive, enthusiasm, project proposals and an engaged group of surgical trainees. The ISRC, for example, has worked closely with the RCSI in the development of the recently launched National Surgical Research Support Centre.[17]

Developing research methodology

We recommend allowing evolution of more complex design and methodology as the organization itself grows. Early in a collaborative's lifecycle, it is imperative that the organization demonstrates capability in project delivery, for it to gain credibility and grow. A research collaborative at inception is unlikely to have the established infrastructure and support to effectively run large, complex studies. Accordingly, groups should resist over-ambitious early targets, and design straightforward, achievable initial projects. The ISRC's first project, PERFECT (PERioperative Fluid management in Elective ColecTomy),[18] was a prospective multicentre cohort study run on a national level, that fostered great learning for the ISRC and allowed familiarization of the Irish surgical community with the collaborative. A competitive public selection process, following peer-review of submitted abstracts, was used to choose the ISRC's next study - RETAINER (RETention of urine After INguinal hernia Elective Repair).[19] RETAINER 1 was created as a prospective study, again observational, but planned for delivery on a global scale, and designed to provide a platform for a qualitative follow-on study, RETAINER 2.

Now that we have developed a robust and well-supported collaborative, with established infrastructure and significant experience gained, we are in a position to deliver our first randomized controlled trial, which is in its final design stages, and to run two projects in parallel. This evolution of research methodology, in tandem with the organization's growth, has been effective and allowed the ISRC to build strong foundations for future expansion.

Recruitment of centres and publicity

Publicity and engagement are essential. For RETAINER, both national and international recruitment campaigns were conducted, with enrolment of centres across 6 continents. This represented marked growth in the ISRC's capacity, with development of global links to other collaborators, and a sustainable international network.

Ethical considerations

In Ireland, historically there has not been a framework for national ethical approval, although one has recently been developed. Therefore, each study to date has had to undergo local review prior to commencing data collection. This has served as a learning opportunity for multiple trainees in engaging with ethical approval processes. However, the process is often cumbersome and can impart significant delays and complexities, particularly if individual ethics boards request different amendments to protocols or patient information leaflets. The key to navigating this is to create a well-designed, clear, peer-reviewed protocol at the outset, and to share all study documentation with collaborators.

Funding and other support

Seeking funding via national and international grant opportunities is important in driving progress. The topic of study may guide funding applications. The RETAINER study was focused on inguinal hernia surgery and outcomes. Accordingly, funding was secured through the European Hernia Society and the British Association of Day Surgery. Funding processes can be timely, and well-constructed applications are crucial. Our experience is that a designated Financial Officer should lead this, with focused committee discussions to consider all potential costs at an early stage. Indirect support from senior and affiliate colleges and organizations (e.g., RCSI) incorporating venue use, statistical support and data collection software has been instrumental to the ISRC. National bodies in other jurisdictions may similarly consider supporting trainee-led collaboratives.

Mentorship opportunities

Mentorship from experienced external senior colleagues helps delivery of research and navigation of obstacles. Furthermore, peer research mentorship within the research group, with a 'learning from each other' philosophy, arises, as trainees with varying levels and types of research experience, from diverse clinical backgrounds, unite. This can significantly support individual trainees' professional development. As the ISRC has grown, we have also identified opportunity to develop designated roles for junior trainees, incorporating research and leadership mentorship. Within a supportive environment, junior trainees may personally and professionally develop, overcome the anxiety of approaching unfamiliar tasks, and reach their full potential. Moreover, it ensures succession and longevity of the collaborative, as the next generation is supported to succeed.

Project management

The steps in executing a collaborative project are presented in Figure 2, and outlined below. We acknowledge that the order in which they are initiated may vary slightly between studies, and that some steps may be conducted simultaneously.

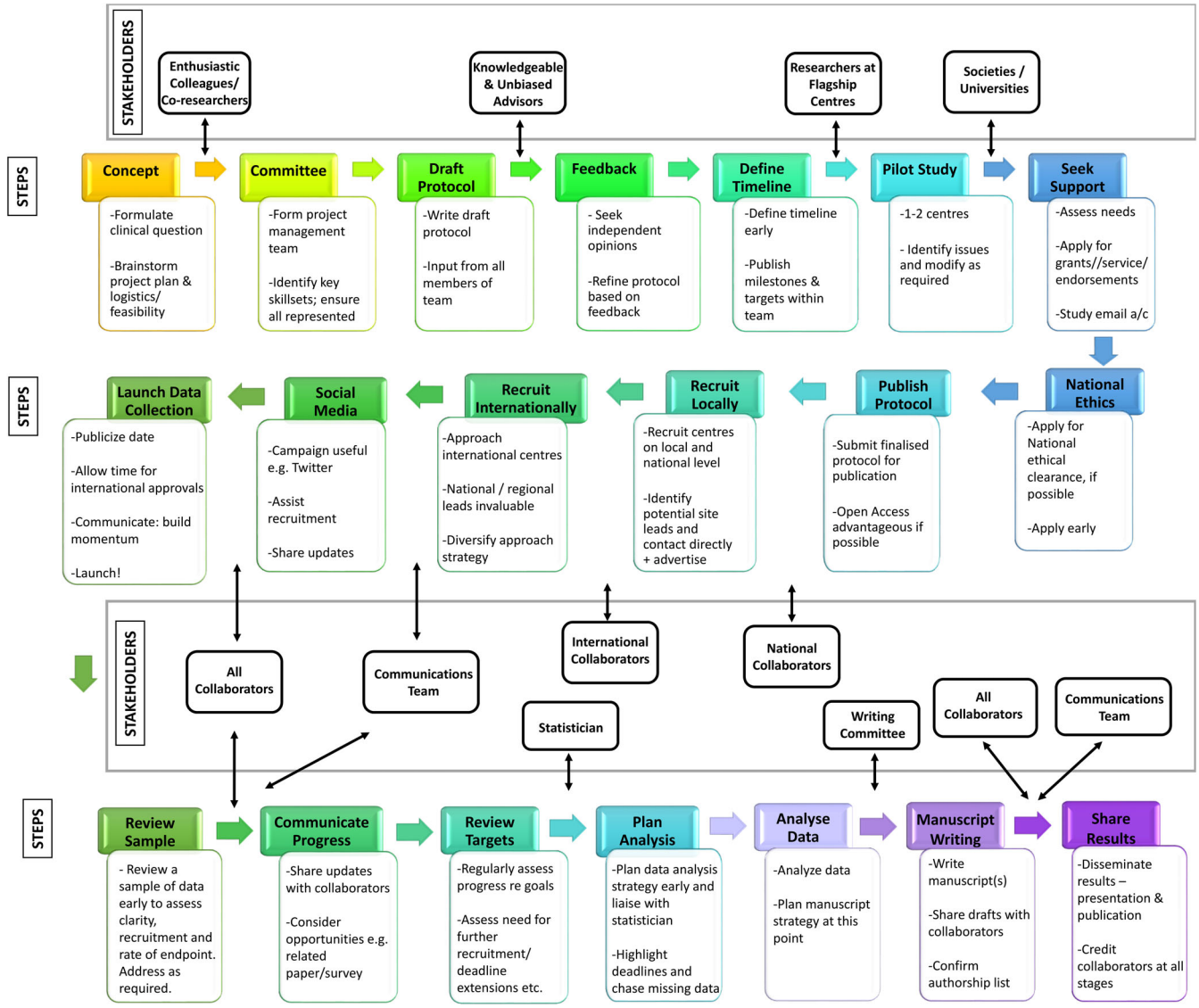

Fig. 2. Steps in delivery of a collaborative study.

Concept

• Brainstorm a general concept of study design from an idea or clinical question. Carefully consider the appropriateness of applying a collaborative model. Be mindful that some research projects may not benefit from multicentre collaboration, or may be unfeasible in this format.

Committee

• Create a project management team. We advise recruitment of a diverse group with a range of skillsets. External, methodological/ statistical expertise will often be required – arrange this at the outset.

• A dedicated study email account should be created, with named committee members responsible for communication.

Draft protocol

• Write the first draft protocol early, to focus the team on moving from an idea to an actionable plan, and allow potential obstacles to become visible.

Feedback

• Seek formal independent feedback on the draft protocol (internally and externally) from a diverse range of knowledgeable and unbiased advisors, for example, consultant mentors and a statistician. Make agreed amendments.

Define timeline

• Create and share a visible timeline early on in the project, with targets and milestones highlighted. This is useful to maintain focus and momentum, even if adjustments are required as the process unfolds.

Pilot study

• Consider running a small-scale pilot study, to test methodology and ensure comprehensibility of information and feasibility of data collection. Enrol data collectors independent of the project management team, to assess generalisability.

Seek support

• Discuss the collaborative and the project with the Royal College or similar professional body in the jurisdiction, if possible. Consider grant applications based on anticipated requirements.

National Ethics

• If a National Ethics committee exists in the country of study origin, submit an application. If approved, this will make enrolment of national centres smoother, and may provide some reassurance to international review boards.

Publish protocol

• Aim to publish the finalized protocol. Submission to a peer-reviewed journal may result in opportunities to further improve the protocol. Alternative options are publication in a pre-print archive or on a collaborative group's website. Open access publishing is advantageous where possible, to maximize accessibility.

Recruit locally

• Begin recruitment early, particularly if review by individual research ethics committees is required. We advocate both contacting potential participants in other centres directly, and advertising the study broadly to offer equal participation opportunities, and to allow newcomers to the network to become involved.

• One challenge we have come across as a trainee-led collaborative, is the fact that trainees move hospitals at frequent intervals during their training in Ireland and the UK. We have learnt to approach this by recruiting trainees and centres soon after the 'changeover' period, with a vision of allowing each appointed trainee site-lead time to set up and run the study before moving onto his/her next job. This approach will generally work for studies with relatively short data collection periods, which the multi-centre model usually facilitates. Where this has been not possible, we have attempted to coordinate a cross-over model, where a trainee will obtain study approval in one site, and run data collection in another, in which the study has been set-up by the outgoing trainee.

Recruit internationally

• International centres may be recruited by directly approaching known contacts, contacting relevant international societies/organizations and advertising on social media. We strongly recommend a multifaceted recruitment strategy to ensure diverse global representation in the case of an international study. Regional or National leads will be invaluable in recruiting further centres within their region, and in explaining local approval processes and other requirements. With the growth of CR in recent years, such leads may have participated in other collaborative studies and bring a wealth of experience to the table, as well as having a network of regional contacts.

• Translation of study documents using validated methods (e.g., 'backwards-forwards' approach) needs to be considered if recruiting internationally. For adequately funded studies, it may be possible to outsource this to professional organizations, however in studies originating from small/new collaboratives, such as ours, this may depend on the goodwill of bilingual national leads or their colleagues. This should be agreed in advance, and translation work specifically acknowledged in authorship.

Social media

• Use social media to disseminate short, regular updates to a wide audience, and to assist recruitment and ongoing engagement of collaborators. We use Twitter/Facebook for this purpose. Do remember, however, that not all collaborators will engage with social media, and even regular users may miss updates. We advise against overreliance on this medium, but find it a good communication adjunct.

Launch data collection

• Set a launch date far enough in the future to allow completion of most approval processes, balancing this against potential loss of momentum with a very distant date. The communications lead/team should publicize the date and endeavour to garner enthusiasm as it approaches. Due to complexities posed by the COVID-19 pandemic, we realized that RETAINER 1 would be possible to deliver only via a flexible approach. For this reason, we launched data collection for 'ready' centres, whilst approvals and recruitment remained ongoing for others. Although this approach is more challenging to coordinate, we discovered it to be feasible and appropriate in certain circumstances.

Review data sample

• Export a data sample relatively early in the study, to ensure clarity and concordance between linked variables in each patient record. Despite conduction of a pilot study, we have found that previously unidentified issues can occasionally arise with data input or interpretation. If a pattern of responses highlights potential misunderstanding amongst collaborators, a clarification email can be sent to participants to eliminate/reduce future occurrences, and allow collaborators to correct discordant data early.

Communicate progress and engage with collaborators

- Communication is imperative, and discussed further below.
- Additional research opportunities related to the study may emerge (e.g., a review or survey) and collaborators can be invited to engage with these.[20]
- Engage actively with site leads as deadlines approach, to ensure optimisation of data and data completeness.

Review targets

• Assess progress regularly, and measure this against pre-defined targets. Formally reviewing this at regular intervals will allow

intervention if required, with recruitment of further centres or deadline extensions.

Plan analysis

• The endpoints and hypotheses will be determined from the time of protocol writing with statistical input. Review planned analyses during data collection.

Clean and analyse data

• Following the data upload deadline, review data for completeness. Missing data can be pursued with site leads, as above, for a brief period. Remaining incomplete records will then need to be deleted in order to progress the research.
• Clean and analyse data at this point.
• Simultaneously, plan the dissemination/manuscript strategy.

Manuscript writing

• The writing committee, generally comprising members of the project management team, with possible additions, should draft the manuscript(s) intended for publication.
• Finalize the authorship list during this phase. Ensure inclusion of all contributors meeting authorship criteria,[14] and accuracy of names and affiliations. This is both a critical and time-consuming task, that should not be underestimated.
• Collaborators may be invited to review draft manuscript(s).

Share results

• Disseminate results via presentation and publication. Collaborators should be notified in advance of the proposed dissemination strategy and be credited whenever the data is used or discussed.

Communication with collaborators

The creation and maintenance of open communication channels with all participants is imperative to achieve effective and successful delivery of a collaborative study. This can pose a challenge for rapidly growing collaborative projects.

Expectations

There is an absolute necessity from the outset, to clearly communicate and clarify expectations of the organizing collaborative and each participating site. Prior to registration, the required contribution from a site should be clearly defined and communicated, with data quality/quantity/timeline characteristics, mode of data sharing and number of team members eligible for authorship stated. Roles acknowledgeable in authorship should be described, alongside the contribution required for each.[14] For international studies, translation requirements should be discussed and agreed upon.

Ongoing liaison

Collaborators in all sites must be kept updated regarding essential information such as deadline extensions. We also feel it is important to check-in with collaborators regularly and inform them of general progress updates to maintain engagement and momentum. Remember that data collectors in individual sites can easily feel isolated from the main project hub and may even question whether the study is progressing at all. It is also necessary for collaborators to have a means of access to the study management team to address any queries that arise, generally via email or online enquiry form. We have the following tips from our own learning curve:

Regional and/or National and Site Leads: should be appointed early where possible, and their roles communicated. They are invaluable in information dissemination and addressing straightforward queries within their network. Furthermore, their knowledge of local research culture and approval processes are instrumental.

Social Media: for example Twitter, can be a useful means of rapidly disseminating brief updates and maintaining momentum. As above, we caution against overreliance.

Email: We recommend creation of a dedicated study email account. If endorsement of a college or professional body is in place, it may be possible to host this on their domain; RCSI has facilitated this for the ISRC.

A *Communications Team* should be established at the beginning of any collaborative study. This was an important learning point we gained from RETAINER 1, in which >300 centres were registered over a relatively short time-frame, with one project team member managing the communication. This led to short intervals in which capacity was exceeded and delays in email responses evolved, which we would hope to avoid in the future. For a large global study, we suggest assignment of at least two team members to the study inbox, one team member to the social media account and two team members to the data collection platform (e.g., REDCap™).

Future proofing

Sustainability is key in establishing a surgical trainee collaborative. We believe there are a few key elements to this. Concrete links with stakeholders, such as national bodies, organizations and individuals in permanent job roles should be made early. A constant drive must be maintained to recruit and nurture new talent, particularly within junior surgical trainees. These individuals should be mentored and supported to grow and become the collaborative's future leaders. Finally, successful execution of studies will make a collaborative more robust and help to guarantee its future.

Summary

The true power of collaboration lies in the ability of surgeons and trainees working together to produce a research product greater than their individual capacity, with true meaningful impact for patients. Furthermore, combined projects across multiple terrains produces results generalisable to diverse geographic, cultural and social groups. Trainee-led surgical research collaboratives have emerged in recent years as dynamic forces with capability to greatly influence the surgical research landscape. We have shared the evolution of the Irish Surgical Research Collaborative from an idea to entity and discussed execution of our first collaborative projects. Key learning points for us have been to establish a core committee of enthusiastic trainees

with defined roles, to elicit support from national bodies and specialty associations and to engage consultant mentorship at an early stage. Forging links with other collaboratives is crucial for effective expansion. Early projects should be straightforward and achievable. The importance of effective communication with collaborators cannot be overemphasized, and project management teams should designate adequate personnel to ensure this. Appropriate recognition for the contribution of all collaborators is paramount. New talent should be continuously recruited to the organization, with an emphasis on attracting both diverse skillsets and junior colleagues seeking mentorship, and sustainability of the collaborative must be prioritized. We feel strongly that collaboration will play a major role in the future of surgical research, with its full potential yet to be uncovered. We hope that our experiences will be useful to others beginning this collaborative journey.

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Author contributions

Stefanie Croghan: Conceptualization; data curation; formal analysis; writing – original draft; writing – review & editing. **Helen M Mohan:** Conceptualization; formal analysis; validation; visualization; writing – review and editing. **Jarlath C Bolger:** Conceptualization; data curation; formal analysis; methodology; validation; writing – original draft; writing – review and editing. **Michael R. Boland:** Project administration; writing – original draft. **Liga Akmenkalne:** Investigation; writing – original draft. **Christina A. Fleming:** Conceptualization; methodology; project administration; supervision; validation; visualization; writing – original draft; writing – review and editing.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1: Supporting Information

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