

New developments for the delivery of plastic surgical research in the UK

The current state of play in plastic surgery research at home and abroad



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Currently, the organisation of medical research in the UK, particularly its management and funding, is undergoing significant change.¹ The purpose of this article is to make clinicians and scientists with an interest in plastic surgical research aware of the new resources available to them to develop the academic aspect of the specialty. In addition, an overview of the present state of plastic surgery research in the UK is summarised, and comparisons are made with how research is funded and organised in other countries with high research productivity.

1. ESTIMATING INTERNATIONAL RESEARCH PRODUCTIVITY IN PLASTIC SURGERY

In order to estimate the quantity of research originating from different countries, all original papers published over a three-year period (January 2009 – December 2011) in the three plastic surgery journals with the highest impact factor (*Plastic and Reconstructive Surgery*, *Journal of Plastic, Reconstructive and Aesthetic Surgery* and *Annals of Plastic Surgery*) were analysed and the academic institutions from which they originated noted. The number of papers originating from each continent and country are shown in Table 1. The majority of articles

published in the past three years originated from North America (56%) and Europe (35%). In Europe, the country that produced the most original articles was the UK (27%), followed by Germany (12%). This method of quantitative analysis may, of course, be subject

Table 1 Number of papers produced by different countries in plastic surgery journals with the three highest impact factors

	Number of papers
North America	1,325
US	1,234
Canada	84
Mexico	7
Europe	776
UK	206
Germany	94
Turkey	89
The Netherlands	75
France	48
Belgium	28
Austria	28
Spain	26
Switzerland	20
Ireland	15
Norway	13
Finland	12
Greece	11
Poland	6
Denmark	5
Asia	638
Japan	165
China	164
South Korea	113
Taiwan	111
India	32
Singapore	27
Iran	13
Oceania	57
Australia	48
New Zealand	9
South America	33
Brazil	33
Africa	12
South Africa	12

to bias as all three plastic surgery journals with the highest impact factor are published in English.

2. CO-ORDINATION AND FUNDING OF PLASTIC SURGERY RESEARCH IN THE UK

Strategic planning, co-ordination of effort and appropriate funding are required for the progression of modern medical research.² At the moment, however, it is difficult to ascertain the amount and nature of research being undertaken in plastic surgery, who is conducting it and which organisations are funding it. This lack of information can lead to various inefficiencies, including the duplication and misdirection of effort.

In the UK, funding for research can be obtained from government bodies, professional and charitable organisations, and industry. Through contacting various key organisations (British Association of Plastic, Reconstructive and Aesthetic Surgeons [BAPRAS], British Medical Association, Healing Foundation, Medical Research Council [MRC], National Institute for Health Research [NIHR], Restoration of Appearance and Function Trust, The Royal College of Surgeons of England [RCS] and the Wellcome Trust), we estimate that approximately £15 million has been allocated to plastic surgery research during the past three years. On the other hand, without a comprehensive centralised database detailing individual studies that come under the plastic surgery umbrella and the funding made available for them, it is difficult to determine how accurate this estimate is.

2.1 GOVERNMENT BODIES

2.1.1 NIHR

In 2005 the 'best research for best health' proposal advocated the co-ordinated collaboration between National Health Service (NHS) trusts, universities, major funders and industry in order to produce world-class medical research.³ This led to the establishment of the NIHR. Under the NIHR umbrella lie three types of networks, each with their own separate budget:

- topic-specific research networks (TSRNs) for high-priority areas
 - cancer, mental health, dementia, diabetes, medicines for children and stroke
- primary care research network (PCRN)
- comprehensive clinical research network (CCRN).

TSRNs and the PCRN were set up initially to increase research productivity in what were deemed to be high-priority areas in medicine. In 2007, based on the success of these networks, the CCRN was established to cover all other areas of healthcare research. This network is made up of 25 local research groups (comprehensive local research networks [CLRNs]) covering England by region. The main aims of these networks are to integrate research into the day-to-day provision of healthcare by streamlining NHS research management and governance processes.

Each CLRN is hosted by one NHS trust in the region, and consists of a clinical director and core management team. All NHS trusts in the region are members of the CLRN and have a seat on the board. In 2009–2010 the CCRN budget, which comes directly from the Department of Health, amounted to a total of £232 million. Funding is allocated to each of the 25 CLRNs and comprises a fixed and flexible allocation. The latter directly follows research activity, which is related to the number of patients recruited to trials registered on the NIHR portfolio. The amount of money distributed to support the research infrastructure of individual projects adopted on the UK research portfolio is then determined by the local CLRN board.

The infrastructure the CLRN can pay for may include consultant time, research nurse time, research training and research governance time. It is important to note that in order for a study to be adopted into the NIHR portfolio, and therefore be eligible for funding and support, it must have already received funding through national competition. This process acts as a peer review and quality assurance measure. Currently, there

Table 2 National specialty groups

Age and ageing
Anaesthetics
Cardiovascular
Clinical genetics
Critical care
Dermatology
Ear, nose and throat
Gastrointestinal
Health services research
Hepatology
Immunology and inflammation
Infectious diseases and microbiology
Injuries and accidents
Burns
Trauma
Fractures
Wounds
Sports injuries
Rehabilitation after injury
Trauma orthopaedics
Poisoning and self-harm
Metabolic and endocrine (not diabetes)
Musculoskeletal
Nervous system disorders
Non-malignant haematology
Ophthalmology
Oral and dental
Paediatrics (non-medicines)
Public health
Renal
Reproductive health and childbirth
Respiratory
Surgery
Urogenital

are 11 projects related to plastic surgery on the NIHR portfolio. These include studies investigating nanotechnology in burns, genetic markers in skin cancer, topical negative pressure in the treatment of lower limb open fractures and quality-of-life assessment tools following breast reconstruction.⁴

Working together with CLRNs, 24 national specialty groups (NSGs) were created in 2007 to enable collaborative research across a range of diverse clinical areas not covered by the TSRN (Table 3). These operate as

national groups of clinical experts addressing national and local barriers to the delivery of research. Although the NSGs themselves do not have a budget, by having a comprehensive overview of projects related to the specialty, receiving detailed monthly reports and by engagement with CLRNs, they are able to actively manage the CCRN portfolio and offer help to investigators.

Each CLRN can nominate one representative to any NSG. The decision to have a representative on a NSG is based on what is perceived as a local priority, and appears to be influenced by local research strengths and academic priorities. Although specialties such as general surgery, orthopaedics, and ear, nose and throat surgery have representative NSGs, plastic surgery does not. This may be a factor in the relative underrepresentation of plastic surgery related projects on the NIHR portfolio.

Of interest to plastic surgeons is the establishment in 2011 of the NIHR Surgical Reconstruction and Microbiology Research Centre. This centre is based at the Queen Elizabeth Hospital Birmingham (QEHB) and £15 million of funding has been allocated over five years (£5 million each for QEHB and University of Birmingham, Ministry of Defence, and NIHR). With regard to plastic surgery-related projects, the organisation is currently running a trial investigating the use of topical negative pressure in the treatment of lower limb open fractures. In addition, it plans to undertake further research into craniofacial reconstruction and tissue regeneration.⁵

Further information for researchers wishing to utilise the NIHR to support their research can be found at: <http://www.crn.nihr.ac.uk/can-help/healthcare-professionals/>.

2.1.2 MRC

In addition to the money distributed through the NIHR, a proportion of government funding for medical research in the UK comes from the MRC. The MRC receives money from the Department for Business, Innovation and Skills, and is governed by 14 members.

In 2009–2010 the MRC spent £758 million on research. The total amount of money that has been allocated to plastic surgery research during the past three years is approximately £4 million. This money has been used to fund a diverse range of projects that include pharmacological preconditioning of free tissue transfer, the use of stem cells in bone engineering, and hair follicle neogenesis.⁶

Other MRC initiatives include collaborative research partnering between academia and industry – the MRC Industry Collaboration Agreement. Although it is difficult to quantify how much plastic surgery research is funded under this award, translating research into healthcare improvements are key priorities for the MRC.

Another government funding initiative is Innovate UK's Biomedical Catalyst. This is a joint programme between Innovate UK and the MRC, and they have funded plastic surgery-related projects, which include a new technique of visualising blood flow in the skin and other tissues during surgery.

2.2 PROFESSIONAL BODIES AND CHARITIES

National professional and charitable bodies that specifically fund research into plastic surgery and wound healing include BAPRAS, the Healing Foundation, and the Restoration of Appearance and Function Trust (RAFT). Those that fund generic medical and surgical research include the RCS and the Wellcome Trust. In addition to the national organisations listed above, the Blond McIndoe Research Foundation and Restore are two significant regional charities set up to fund projects related to plastic surgery.

2.2.1 BAPRAS and the RCS

At present, there is no national research agenda for plastic surgery that is easily accessible to clinicians and scientists in the field. In order to produce high-quality studies in a timely and cost-effective manner, this situation needs to be addressed. A group of experts, ideally comprising of clinicians, scientists and patient representatives, needs to reach a consensus on the facets in

each area of interest (wound healing, breast reconstruction, hand surgery, head and neck reconstruction, facial palsy, lower limb reconstruction, skin cancer, craniofacial surgery, cleft lip and palate) that are deemed a current research priority.

Following this, time-limited, outcome-directed goals need to be set and this information should be made easily accessible. BAPRAS is an organisation that can help facilitate this and already has a research council in place. It is also in a position to develop links with the NIHR. Certain groups, such as the College of Emergency Medicine, have already developed partnerships with the NIHR so that all research funded by the former automatically becomes part of the NIHR portfolio. This streamlines the process of making use of valuable NIHR resources. Developing a similar partnership with the NIHR so that approval by BAPRAS represents peer review and quality assurance that a study is of high enough quality to be adopted into the NIHR portfolio should be an aim of the organisation in the near future.

The RCS has started an initiative to develop a nationwide surgical clinical trials portfolio. This includes a section for trials in reconstructive surgery. Linked to this enterprise, BAPRAS and the British Society for Surgery of the Hand have appointed a specialty lead to help promote the initiation of clinical trials and encourage nationwide multicentre co-operation in plastic surgery research. It is important that as many trials as possible are registered in this online portfolio so that co-ordination of effort can be undertaken, enabling the optimal use of resources. To get involved with ongoing trials or to register a new trial, further information can be found at: <http://reconstructivesurgerytrials.net/>.

With regard to funding, over the past three years, BAPRAS has allocated £16,000 to individual research projects in plastic surgery through the Paton–Masser memorial fund. In addition, BAPRAS has donated £75,000 to the Healing Foundation to support ongoing research.

2.2.2 Wellcome Trust

The Wellcome Trust is an international charity based in London. It was established in 1936 and spends approximately £600 million per year on medical research. During the past three years, £880,000 has been allocated to research related to plastic surgery. Funded projects have included work investigating the genetic basis of craniofacial malformations, radioprotection of free flaps using gene therapy, and the three-dimensional analysis of facial dysmorphology.

2.2.3 Healing Foundation

The Healing Foundation was established in collaboration with BAPRAS in 1999. This charity is the largest organisation that specifically funds research into improving the lives of patients with disfigurement. Substantial funds have been donated by the Healing Foundation into developing research centres for wound healing and tissue regeneration, cleft and burns.

In 2005 the Healing Foundation and the University of Manchester jointly committed £10 million over 25 years to establish a centre to investigate wound healing and tissue regeneration. In 2011 the University of Manchester was awarded a further £2.4 million to establish the infrastructure to support a range of clinical trials and other well designed projects in cleft lip and palate. At the same time, the University of Bristol was awarded £2.4 million to establish a biobank of DNA material for children born with clefts, which can be used in the future as a valuable resource for epidemiological and genetic studies. Also in 2011, following competitive external peer review, it was decided that centres for burns care research would be established in Bristol and Birmingham. The Healing Foundation will donate £1.5 million to each unit over five years with an equivalent amount being put in by the centres themselves.

In addition to these large scale initiatives, the Healing Foundation has allocated approximately £2.2 million to individual research groups undertaking studies in plastic surgery over the last three years.

2.2.4 RAFT

RAFT is an independent charity established 25 years ago, based at the Mount Vernon Hospital in Middlesex, which carries out research in plastic and reconstructive surgery. During the past three years, the organisation has spent approximately £3 million funding projects, which have included the investigation of optimising fat transfer, skin scaffolds and the development of state-of-the-art prosthetic limbs.

2.2.5 Blond McIndoe Research Foundation

The Blond McIndoe Research Foundation is an independent charity based at the Queen Victoria Hospital in East Grinstead. It was established 52 years ago by Sir Archibald McIndoe, and Neville and Elaine Blond. Clinical research interests include burns, soft tissue reconstruction, scarring, fibrosis and contractures, cell spraying and expansion techniques, tissue regeneration, adipose derived stem cells, hypoxia and pH in wounds, melanoma research and patient participatory research. Over the last three years, £2.2 million has been spent on projects in these areas.

2.2.6 Restore

Restore was established in 1991 as a charitable trust for research on burns and reconstructive surgery. Clinical studies are carried out at Stoke Mandeville Hospital, and laboratory research is conducted at universities based in Bristol, London, Manchester and Oxford. During the past three years, this charity has distributed approximately £400,000 to plastic surgery-related research.

2.3 FUNDING THROUGH INDUSTRY

During the past decade, industry has funded approximately 50% of biomedical research in the UK.⁷ Until recently, however, there has been little guidance for researchers on how to go about establishing links with private biotechnology and pharmaceutical companies. At the moment, collaborations between industry and plastic surgery researchers are often the result of companies seeking

out and approaching surgeons carrying out operations in the relevant field of interest. Nevertheless, as private companies often restrict what is put out in the public domain, reciprocal help for clinicians wishing to gain the support from the appropriate firms is difficult. Consequently, partnerships are not often forged at the early stage of research development.

Despite this, the collaboration of clinicians, scientists and industry early on can be beneficial in terms of not only targeting research according to clinical need but also undertaking 'mechanism of action studies', which are increasingly being required by regulatory authorities before products can come on to the commercial market. UK-based companies that currently have a particular interest in improving wound healing and have been involved in the development of experimental and clinical studies relevant to plastic surgery and wound healing include PharmEcosse, Intercytex, Shire Regenerative Medicine, GlaxoSmithKline, Pfizer, Baxter and Galderma.

The NIHR has set up initiatives to help forge collaborations between industry and academic institutions. In the North West of England, the Exemplar Programme was set up in 2007 with the remit to streamline the NHS permission process for commercial studies. An analysis of 18 studies set up through this programme showed a greater than twofold reduction in the time between the submission of the local research and development form and study start-up.⁸

The NIHR portfolio now includes approximately 460 industry studies, with almost 40% of all UK commercial clinical trials being included in the portfolio in 2009.⁹ The number of active studies has increased from 18 in 2006–2007 to over 14,000 in 2009–2010.⁹ In plastic surgery, collaboration between researchers and commercial companies has previously proved beneficial in advancing the field. Having an easily accessible national database of information detailing past and ongoing industry supported studies would help facilitate the matching

of companies with the relevant clinicians and academic institutions, allowing collaboration at an early stage.

3. INTERNATIONAL RESEARCH

The US publishes the highest volume of plastic surgery-related articles worldwide. In Europe, after the UK, Germany is the country from which the most articles originate. The following gives an overview of research funding in these two countries with high research activity.

3.1 THE US

The high output of research that originates from the US is in part owing to the large amount of money available for funding. For example, the National Institute of Health (NIH) has earmarked \$200 million dollars as 'stimulus money', which will be used specifically to fund areas relevant to the field of plastic surgery, including clinical studies investigating outcomes following reconstructive surgery as well as research into regenerative medicine.¹⁰ The Research Project Grant (R01) is the original grant mechanism used by the NIH. It is an award made to support a specified project to be performed by the named investigator in an area representing the investigator's specific interest. Annual grants of \$25,000–\$250,000 are made to cover the costs of running the project.

In addition to the money made available through the NIH, the US Department of Defense also sponsors research in plastic surgery. The creation of the Armed Forces Institute of Regenerative Medicine (AFIRM) in 2007 resulted in \$85 million of funding being made available. AFIRM has been of particular interest to plastic surgery researchers and current clinical trials that are underway include autologous fat transfer, minimally invasive reconstructive surgery, face transplantation, tissue regeneration, scar prevention and the use of cultured keratinocytes.¹¹

The American Society of Plastic Surgeons (ASPS) has an active role in promoting research in the specialty. Through the

National Endowment for Plastic Surgery, it has provided approximately \$1.5 million for various projects between 2006 and 2010. The amount the ASPS is giving for research is increasing year on year and in 2012 it awarded nearly \$625,000 to 28 investigators. The majority of the studies funded are pilot studies that serve as a starting point for larger scale projects, which can then be funded by the NIH.

The Plastic Surgery Foundation in the US, in collaboration with the American Association for Hand Surgery, the American Council of Academic Plastic Surgeons, the American Society for Peripheral Nerve, the American Society for Reconstructive Microsurgery and the Plastic Surgery Research Council, also awards jointly funded grants and promotes innovative research in hand surgery, academic plastic surgery related to research, peripheral nerve research and microsurgery. In 2013 the Plastic Surgery Foundation allocated nearly \$772,000 to 34 investigators to support the newest, clinically relevant research in plastic surgery.

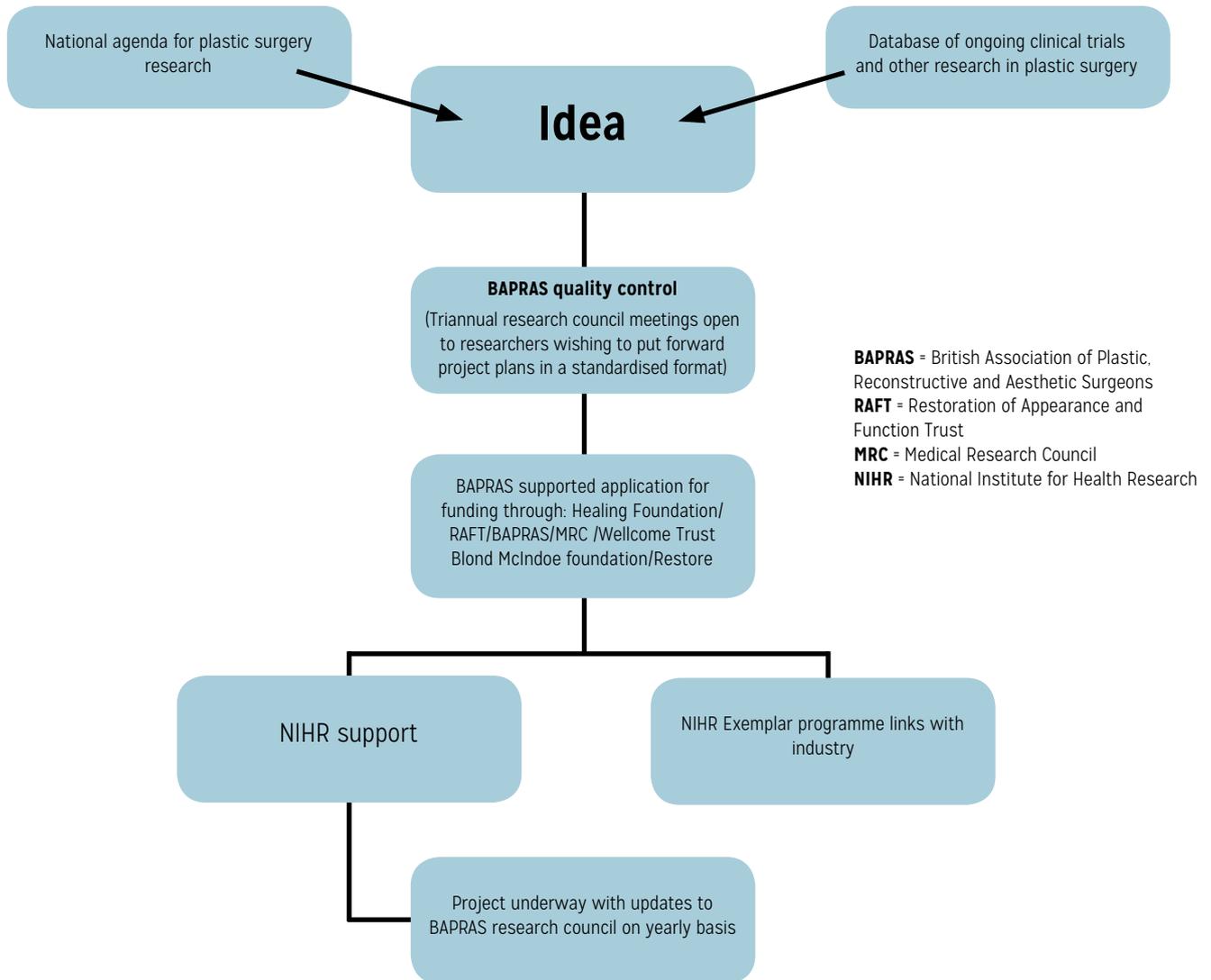
3.2 GERMANY

In Germany, those with an interest in research can access various sources of support. This includes governmental bodies, professional bodies, various foundations, fellowships and industry.

The main governmental bodies are the Deutsche Forschungsgemeinschaft (DFG; German research society) and the Bundesministerium für Bildung und Forschung (BMBF; ministry for education and research). The national professional body for plastic surgeons in Germany is the Deutsche Gesellschaft der Plastischen, Rekonstruktiven und Ästhetischen Chirurgen (DGPRÄC; German society for plastic, reconstructive and aesthetic surgeons).

The DFG supports research in all areas of science. This includes singular projects, multi-institutional projects and excellence awards for outstanding research results as well as support of scientific infrastructure and scientific contacts.¹² Online applications

Figure 1 Proposed flowchart for development of ideas into research



for individual studies are limited to German nationals and go through a competitive selection process. Successful applications are granted a specific amount of financial support, which is often staggered and dependent on progress reports.

The BMBF sets the areas and topics for research, which are based on the national health political needs and aims. These change over time. The underlying goal is to put research results from basic science and clinical trials into clinical practice quickly.¹⁵ At present, the BMBF provides support for health research in the areas of personalised health treatment, preventive and nutritional

research, and endemic diseases. There is currently no support for research in the areas of plastic, reconstructive and aesthetic surgery.

The DGPRÄC represents the general and professional interests of plastic, reconstructive and aesthetic surgeons in Germany. The organisation is made up of 16 regional associations with an appointed chair and deputy for each region.¹⁴ The elected representatives have links to local authorities, political institutions and the media.

In addition, the DGPRÄC supports clinicians and scientists who want to get involved in research. Via the website, researchers can

access national running projects in plastic surgery. Furthermore, contacts are provided to encourage collaboration between different units nationwide. Of note, the DGPRÄC does not help fund new research projects and financial support is limited to a few prizes for excellent performance (Polytech travel bursary: €2,500, science prize: €3,000, plastic surgery journalist prize: €3,000).

CONCLUSIONS

In the UK, certain fields in medicine have developed very successful national research networks. The most notable of these is the NIHR Cancer Research Network. This

organisation is made up of 32 local research networks covering the UK by region. By creating a partnership between government departments, charitable organisations and industry, it has enabled the successful promotion of cancer research, which has led to significant improvements in patient outcomes. In order for a similar research infrastructure to be established in plastic surgery, improved strategic planning and co-ordination of effort is needed. The fact that the RCS, together with BAPRAS, is beginning to compile a database of ongoing and completed trials is a positive step. A similar system is in place in Germany, allowing collaboration between units nationwide and avoiding duplication of effort.

The most significant change to healthcare research management in recent times has been the introduction of the NIHR. Despite the economic downturn, there is now a significant amount of money available to support high-quality research. In fact, this is probably the only area of NHS spending that, in real terms, has seen an increase in budget. However, currently there are relatively few plastic surgery-related projects on the NIHR portfolio. This may be owing to the absence of an NSG representing the specialty and unawareness of the help that can be provided.

Many NHS trusts are now discouraging clinicians from spending time on non-NIHR portfolio research as the trust has to fund the full cost of such research, whereas a large proportion of the cost of portfolio projects is funded by the CLRN. In addition, as future funding directly follows patient participation in portfolio trials, there is an added incentive for trusts to register all studies with the NIHR. The links that can be established with industry through the NIHR Exemplar Programme are potentially another huge financial incentive for researchers wishing to develop ideas into tangible diagnostic and treatment products.

With such significant changes in the national organisation and funding of research already underway, it is going to become increasingly difficult to undertake

small-scale, self-funded clinical projects. It is therefore imperative that enthusiastic scientists and clinicians with an interest in plastic surgery put themselves forward for positions on CRLN boards, and endeavour to make the specialty a research priority in the NIHR. In addition, it would be beneficial for BAPRAS to act as a bridge between researchers and the NIHR. With this organisation, in conjunction with the RCS, already taking the lead to establish a national trials support network, the development of a well-funded infrastructure that will promote successful research in plastic surgery should be achievable (Figure 1).

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