

SRUK Research Strategy

2019-25



“Over the past 30 years there have been many advances in our knowledge of Scleroderma and its various subtypes, but Scleroderma has still not given up all its secrets, and until it has done, further scientific research will be crucial, and the support of SRUK enormously valuable.”

Professor Dame Carol Black

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ABOUT US

Scleroderma and Raynaud's UK is the only UK charity dedicated to improving the lives of people with Scleroderma and Raynaud's.

Our vision is a world where no-one has their life limited by Scleroderma and Raynaud's.

Our mission is to improve the lives of everyone affected by Scleroderma and Raynaud's. We achieve this by investing in research, improving awareness and understanding of the conditions and providing information and support to all those affected.

Our values are central to who we are and the way we work. We are:



FOREWORD

Scleroderma and Raynaud's UK is the only UK charity solely dedicated to improving the lives of people living with Scleroderma and Raynaud's Phenomenon.

Scleroderma is a rare, complex multi-system disease with Raynaud's often being a first presenting symptom. For many people the condition is life threatening, but it seriously impacts the quality of life for everyone.

In the last thirty years, thanks to research, our understanding of the disease has increased and we have seen improvements to the diagnosis, treatment, and management of Scleroderma and Raynaud's.

Over this period the charities' combined focus on funding research has supported many researchers in their quest to understand what causes scleroderma and how to treat it effectively, leading to better survival outcomes for patients. However, there is still a long way to go.

Our vision for the future is ambitious but simple. No person with Scleroderma or Raynaud's should suffer from their condition. We are determined to drive forward research to ensure people will be diagnosed quickly, and given the perfect treatment that manages their presentation of the condition.

To better understand the role that SRUK can play we co-produced a research strategy with members of our patient and research communities. As part of the process, we identified some of the biggest barriers to driving progress in research. These are a lack of coherent and consistent datasets; few clinically validated molecular markers to enable diagnosis and stratification and the lack of therapeutic intervention to address the condition as a whole.

We believe there is an opportunity for us do things differently and to be more entrepreneurial and commercial, in relation to research. To achieve this, we will work hard to leverage external investment, we will form partnerships to drive innovation and we will seek a return on investment to ensure that any SRUK developed & funded intellectual property is protected and used to deliver a return to be re-invested in our research.

We believe that the day will come soon when not a single person will have their lives limited by these painful and debilitating conditions and that it is research which holds the key to a better future.

Sue Farrington
Chief Executive, SRUK



ABOUT THE CONDITIONS

Raynaud's Phenomenon

Raynaud's phenomenon (also referred to as Raynaud's syndrome - or just Raynaud's), is an extremely common but under recognised condition, affecting 10 million people in the UK today.

Raynaud's is caused by an oversensitivity of small blood vessels to temperature changes such as exposure to the cold. The blood vessels constrict, reducing the blood and oxygen supply to the extremities causing the characteristic whitening of affected body parts such as fingers and toes.

Upon warming, the blood vessels relax back to their normal width, allowing the blood to flood back to the oxygen starved tissue, often triggering sharp bursts of burning pain. This is known as a Raynaud's attack and many people can experience these attacks several times a day. Raynaud's can be subdivided into two types: primary or secondary Raynaud's.

Primary Raynaud's is by far the most common form and can be more manageable, but there are some people who experience more severe

symptoms that can be extremely painful, debilitating and affect their quality of life.

For people who are more severely affected, Raynaud's can be associated with an underlying cause, such as an autoimmune condition. This is referred to as secondary Raynaud's, which accounts for around 10% of all cases.

The condition may lead to ulcers developing on the fingers and toes, eventually leading to a calcium build-up in the soft tissue that can be particularly painful, a condition known as calcinosis. Secondary Raynaud's affects 97% of people with Scleroderma and is often the first sign of this serious condition. At present, there is no cure, only treatment to help alleviate symptoms.





Scleroderma

Scleroderma is a rare autoimmune condition where the body's immune system becomes overactive and attacks healthy tissue. It affects about 19,000 people in the UK and 2.5 million worldwide. Scleroderma is under-recognised and poorly understood. There is no cure for this life-limiting and disabling condition that severely impacts upon patients' quality of life.

Scleroderma literally means 'hard skin', which can be one of the first noticeable symptoms of the condition and is caused by the body producing too much collagen. This excess collagen may also affect joints, tendons and organs and can stop the body from functioning normally. There are two main types of Scleroderma: localised Scleroderma and systemic sclerosis.

Localised scleroderma

The two types of localised Scleroderma are called **morphoea** and **linear** Scleroderma.

In **morphoea** Scleroderma, hard, painless patches of smooth, shiny skin are seen on the trunk or another part of the body, usually with no other symptoms or problems.

In **linear** Scleroderma, a line of hard, shiny skin appears along an arm or leg. This skin is miscoloured or scarred and often feels tight and uncomfortable. Linear Scleroderma can affect growth in children.

Systemic Sclerosis

There are two types of systemic sclerosis, and both affect the whole body to a varying degree.

Limited systemic sclerosis usually progresses slowly, visibly affecting the hands and arms below the elbows and the feet and legs below the knees, as well as the face. The condition can cause thickening of the skin, and problems with the gastro-intestinal tract such as heartburn and difficulty swallowing. People may live with Raynaud's for many years before developing other symptoms.

Diffuse systemic sclerosis usually affects the whole body, and there is a risk of life-threatening complications involving the heart, lungs, and kidneys. Common symptoms include tiredness, joint pain and stiffness.

OUR HERITAGE: A 30-YEAR TRACK RECORD

SRUK was formed in 2016 following the merger of the Raynaud's and Scleroderma Association and the Scleroderma Society. Over the last three decades, these two founding charities funded over 100 research grants, spending more than £10 million on cutting-edge science.

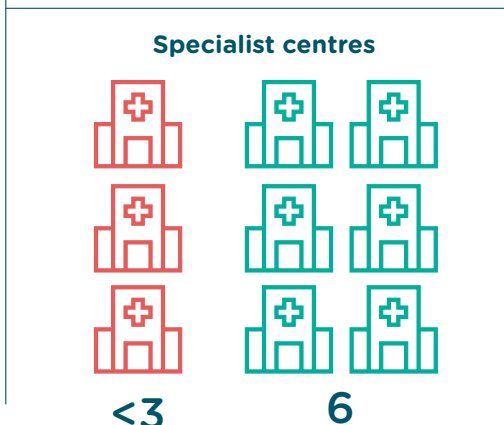
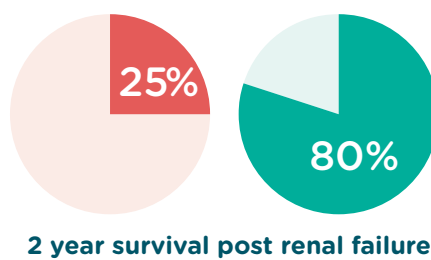
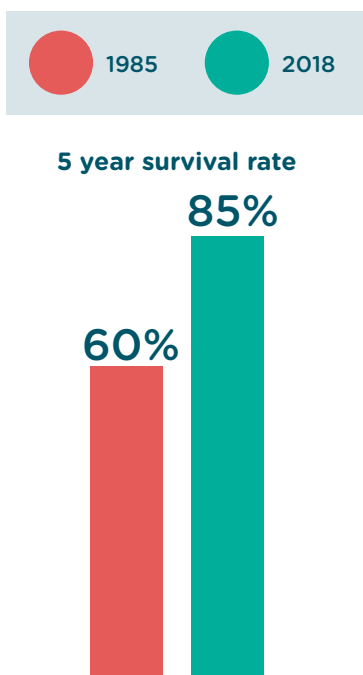
This funding has contributed to:

- Laying the foundations for a strong UK research community
- Enabling clinicians to detect these conditions earlier
- Developing a more effective classification of the various forms of these conditions to enable better diagnosis
- Developing the best treatments available
- Increasing understanding about the causes of these conditions

Our founding charities funded science at all levels, from building our knowledge about the very basic mechanisms underlying the conditions through to pioneering new methods of earlier detection and diagnosis.

This work, carried out through our communities working together, has helped transform the outlook for people living with the conditions. Survival outcomes and quality of life have significantly improved, and there are now more treatments available.

Research has been the key to improving the rate of survival five years post diagnosis, resulting in an increase in survival from 60% to 85%. Research is the reason that renal crisis is no longer the leading cause of mortality, and it's the reason why we now have more than 10 types of treatments that are available to treat the complex symptoms of Scleroderma and Raynaud's.



DEVELOPMENT OF OUR RESEARCH STRATEGY

Research over the last 30 years has put us in a stronger position to accelerate the benefits to the patient sooner rather than later. However, despite this progress there is still much more that needs to be done, with 45% of people waiting at least three years to be diagnosed, and 25% unable to work within five years of their diagnosis due to their condition.

We need to ensure that the research we fund continues to benefit the patient community.

As a patient-centred organisation we co-produced our research strategy with

members of our patient community plus our clinical and research communities, forming the Patient Community Research Panel (PCRP), and the Research Strategy Advisory Group (RSAG).



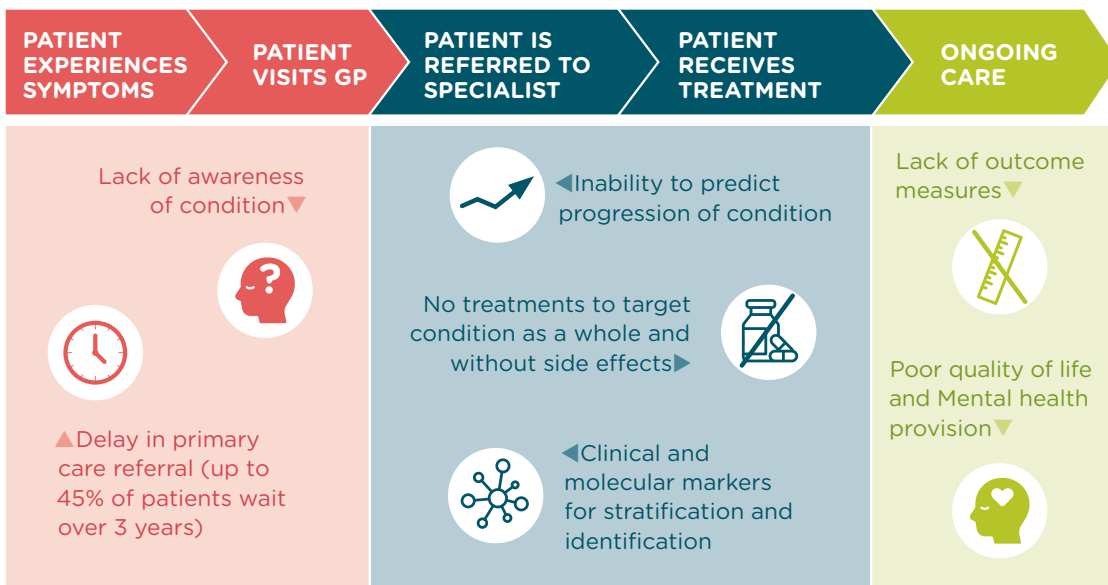
The process used to develop our Research Strategy.

Phase 1 – Understanding the current research landscape

SRUK carried out a comprehensive review of the current UK and international research landscape, to explore how this related to the broader patient journey and the needs of the UK patient community. SRUK interviewed key members of the clinical and research community as well as reviewed published research and the latest research findings presented

at scientific conferences. From this process, several key research gaps were identified within the existing research landscape.

Working in partnership with the PCRP, SRUK built up a picture of the typical patient journey, from the first symptoms to diagnosis, referral and ongoing care. **The barriers and challenges patients currently face are outlined in the diagram below.**



Critical research gaps and their impact on patient experience

As part of our patient-centred approach, the emerging gaps in research identified by research leaders were aligned with the most relevant area of the patient healthcare journey.

Primary care: Patient experiences symptoms and visits their GP

It is still unclear what causes Scleroderma and Raynaud’s. Unlike other rare diseases like cystic fibrosis, research shows it is unlikely that a single inherited genetic mutation is responsible. The complexity of Scleroderma suggests that multiple factors, including a person’s genetics,

their immune system and past environmental exposure, may lead to onset of the condition.

Currently, there are few ‘red flags’ or diagnostic markers that indicate early stage Scleroderma, let alone those that can be used in a primary care setting to enable appropriate referral. More research is needed to establish these markers and identify patients in the pre-disease state.

Secondary care: Patient is referred to a specialist and receives treatment

The complexity of Scleroderma means that there needs to be more refined strategies to stratify, or categorise, a patient's disease at the molecular level. This includes markers that can indicate early and specific organ involvement, as well as indicate which organs may be affected in the future.

Whilst many biomarkers have been identified in the literature, few of these have been clinically validated to enable their usage in the clinic where the need is highest. Additionally, clinical research into the usage of the markers to predict progression of the conditions over time has been limited to date, therefore impacting the ability to predict the progression of the condition.

In recent years there has been increased interest from the pharmaceutical industry resulting in progress into treatments aimed at various aspects of Scleroderma such as pulmonary hypertension or liver fibrosis. However, despite these advances there is still a lack of effective treatments to treat the condition. Furthermore, patients may experience a multitude of side effects in response to existing treatments which can significantly reduce quality of life.

Ongoing care:

There are few objective outcome measures for determining efficacy of treatment, with little research conducted into identifying best practice for patient reported outcome measures. This is due, in part, to the complex nature of the condition and the relative lack of validated biomarkers that can act as objective diagnostic measures.

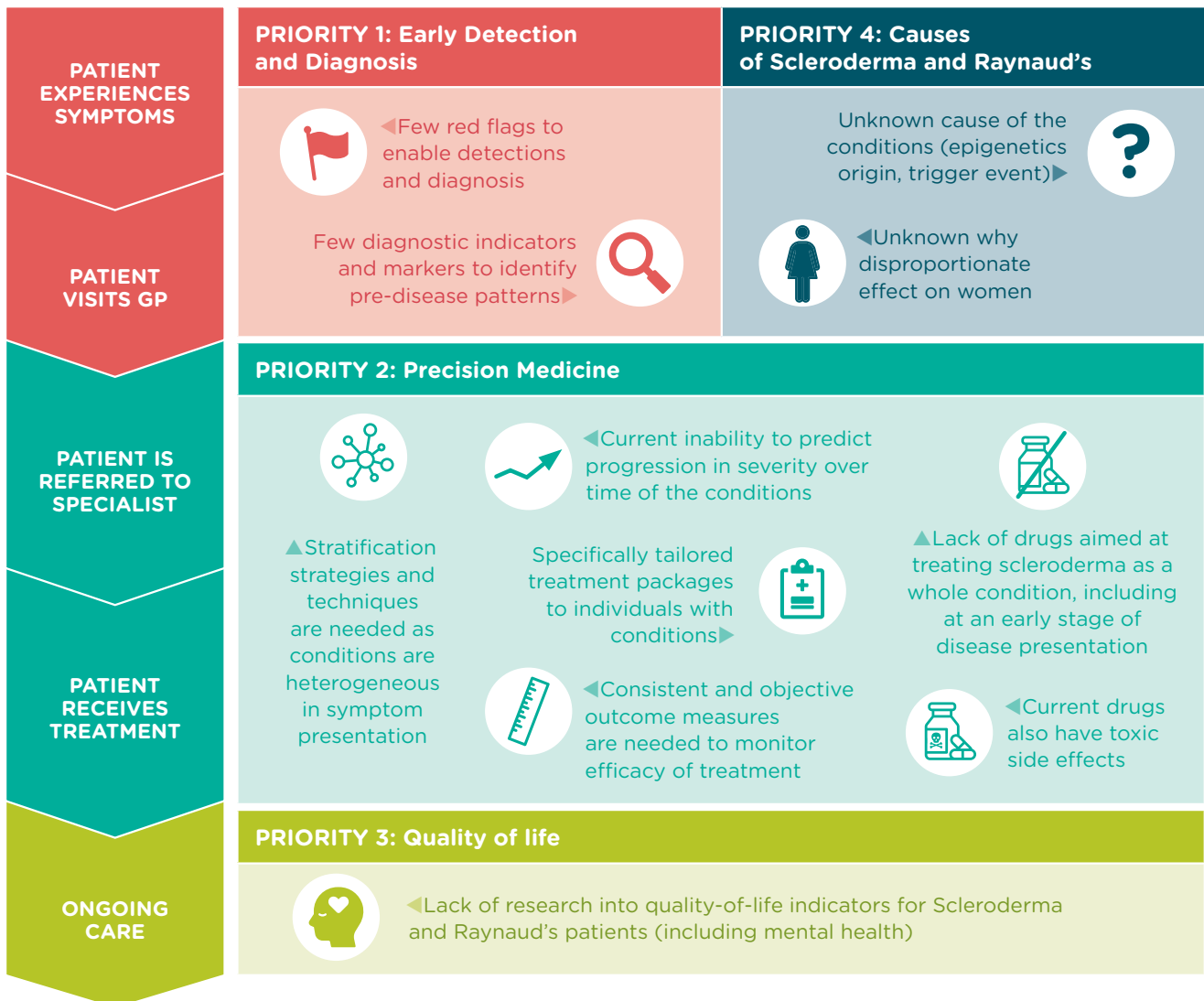
Research over the last 30 years has focused on identifying biological aspects of the condition, which, when targeted, can drastically improve Scleroderma survival rates. Survival rates have now significantly improved, but current research is still focused heavily on biological intervention. Quality of life has shown to impact survival rates, however, due to lack of research, there are few recognised 'quality of life' indicators.

Emerging research themes

Mapping the research gaps to the patient journey led to the identification of four overarching research themes. These themes were prioritised by members of the PCRPs according to their importance in improving the patient journey of someone living with Scleroderma and Raynaud's. **The four research themes which underpin the SRUK research strategy and their ranking by patients is shown in the box below.**

- 1 Accelerating **PRECISION MEDICINE** so that patients can receive a tailored package of treatment and care that is unique to their condition
- 2 Enabling **EARLIER DETECTION** to ensure that more people receive life-saving drugs at early stages of the conditions
- 3 Improving **QUALITY OF LIFE** so that people can live longer and healthier lives
- 4 Understanding the **CAUSES** of scleroderma and Raynaud's to enable the development of new treatments or a cure

Research gaps identified by the research leaders in our scientific advisory group are shown mapped onto the prioritised research themes in the figure below.

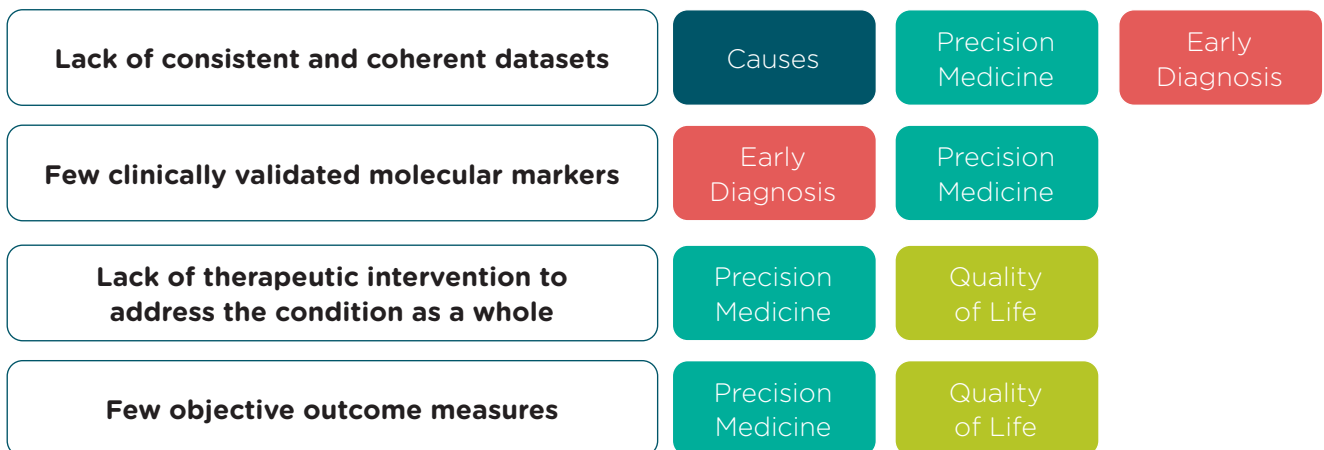


Understanding the barriers to research

Once the key research themes had been identified, it was important to understand what the challenges were in accelerating these themes. SRUK held a multi-stakeholder workshop of patients, researchers, and clinicians, where four key challenges emerged as being the significant blockers to progress. These were:

- A lack of coherent and consistent datasets.
- Few clinically validated molecular markers to enable diagnosis and stratification.
- A lack of therapeutic intervention to address the condition as a whole.
- A lack of reliable objective outcome measures making it difficult to assess whether treatments are effective.

These barriers are shown in the figure below alongside the research themes which they affect.



Phase 2 - Identifying the solutions

In addition to patients, clinicians and researchers, the life sciences industry is a key element in generating a solution for Scleroderma and Raynaud’s.

SRUK met with a number of biotech and pharmaceutical companies to understand how we could work more effectively in conjunction with our clinical research community. We looked into solutions our organisation could develop as part of our Research Strategy, to accelerate progress in the delivery of better treatments.

We met with Directors and senior members of medical research charities such as Alzheimer’s Research UK, Autistica and Scar Free Foundation, to understand and take inspiration from the innovations in funding that many of these organisations had pioneered.

Phase 3 - Finalising the research strategy

All stages of the Research Strategy development were overseen by our Research Strategy Advisory Group (RSAG). The final version of the strategy was presented to the RSAG and the PCRCP for comment prior to endorsement.

The themes which underpin the SRUK Research Strategy will be discussed in greater detail in the next section alongside real patient stories which demonstrate the transformative impact that advancing these areas could have on those living with Scleroderma and Raynaud’s.

OUR RESEARCH THEMES

The following sections explain the importance of our research themes from the perspective of those living with scleroderma.

Early detection and diagnosis

Like many chronic, progressive conditions, the sooner Scleroderma is diagnosed in a patient, the better the prognosis for the individual. The first three years after the initial onset of Scleroderma are thought to be the most damaging, presenting a critical window of opportunity for intervention to improve prognoses. Despite this, it takes an average of five years for a person with Scleroderma to receive a diagnosis and access appropriate care and treatment.

Many of our community members will identify with Georgina's story (opposite), highlighting the need for better and more clearly defined diagnostic pathways to facilitate early detection. Indeed, our scientific and community leaders believe there is scope to accelerate progress within earlier detection to safeguard our community's wellbeing.

Our ambitions:

- Work with primary and secondary healthcare professionals to raise awareness of Scleroderma.
- Work with clinicians to improve the classification of Raynaud's, to highlight those at risk of progressing to autoimmune connective tissue diseases like Scleroderma.
- Fund research to accelerate the development of tools and techniques to identify the indicators of Scleroderma earlier.
- Identify and validate molecular signatures of early-stage Scleroderma, such as blood and/or tissue biomarkers.
- Help to develop new tools and ways of diagnosing Scleroderma and Raynaud's.
- Look at innovative ways that we can use data to improve diagnostic practices.

Georgina's Story

Georgina faced multiple barriers to receive her ultimate diagnosis of systemic sclerosis. In the 18 months that her symptoms were overlooked, her condition deteriorated rapidly and the impact on her life was inescapable. After many failed attempts and nearly giving up hope, it was in Poland that she eventually received her diagnosis and relevant treatment in a matter of days.

Despite her wishes to return home, her family convinced her to stay in Poland to continue with the care, and after a full year of treatment, she was finally able to come back. The delay to

receiving treatment meant that she was no longer able to use her hands to their previous full capability, and together with the chronic fatigue brought on by the Scleroderma, she had to put on hold her work as a beauty therapist. Georgina now firmly believes that if her Scleroderma had been detected earlier so she could have received effective treatment sooner, her career and personal life would not have suffered to such a dramatic extent.

“

I felt very overwhelmed, I couldn't really process it to begin with. I was very much in denial and angry. I was determined to fly back to the UK and get back to work and carry on as normal.

Georgina

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Kim's Story

Kim's Scleroderma led to her experiencing renal failure and falling into a coma. The expertise of Kim's doctors meant that Kim survived this potentially fatal complication and now enjoys a relatively good quality of life. Having lived with Scleroderma for more than 30 years, Kim has a passion for research and the importance (for it) to focus on patient benefit. Kim is actively involved in European and UK based patient

and research organisations and often lends her perspective to researchers setting up trials of new treatments for Scleroderma. Her involvement on the SRUK Research Committee helps determine which research projects should receive financial support and Kim also enjoys using her time to support others with Scleroderma and Raynaud's through volunteering on the SRUK helpline.



“

Having my kidneys fail as a result of systemic sclerosis was extremely frightening for me and my loved ones. Fortunately, my doctors understood this rare complication and I received expert care and treatment. Without this I would not be here today.

Kim

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Precision medicine

Scleroderma is a highly complex condition which differs between individuals. Some people living with the condition may have incredibly severe symptoms from the outset but remain stable for the rest of their lives; others may at first have mild symptoms but then deteriorate suddenly. Some individuals exhibit severe gastro-intestinal involvement whereas others may develop lung, heart, or kidney complications. Such complexity presents an exciting opportunity to exploit 'precision medicine', the tailoring of treatment(s) to an individual or subgroup of patients, as opposed to a 'one-drug suits all approach'.

Precision medicine is dependent upon the use of robust prognostic indicators to stratify patients into sub-groups, based on their current presentation of Scleroderma and how this might change in the future. Increased knowledge of the various sub-groups of Scleroderma can help doctors assess a person's prognosis, and prescribe treatment(s) to enable the best possible outcomes.

The benefits of precision medicine have already been demonstrated by research conducted in the last 30 years and have facilitated the development of new medications, ranging from vasodilators and immunosuppressants, to more specific drugs that focus on calcinosis and digital ulcers. Treatments for specific organ manifestations have also been developed, such as for pulmonary hypertension and liver fibrosis, following growing interest from the pharmaceutical industry. Investing further resources to fully harness precision medicine offers a multitude of positive outcomes, by enabling medical teams to provide targeted care, improving chances of survival and safeguarding quality of life, and thus it is pressing that efforts are directed towards this area.

Our ambitions:

- Support the identification of genetic, lifestyle and environmental factors, alongside an understanding of how these factors intertwine to impact on a person's Scleroderma or Raynaud's diagnosis and prognosis.
- Fund research to identify signs of organ involvement such as the lungs or gastro-intestinal tract.
- Carry out pioneering work around 'outcome measures,' to evaluate the efficacy of treatments more reliably and explore whether the benefits of treatment outweigh the risks or side effects.
- Invest in work supporting the validation of existing biomarkers plus the identification of new ones, which can be used to support patient care and identify risk of future organ involvement.

Causes of Scleroderma and Raynaud's

A common question from patients is, 'What actually causes Scleroderma and/ or Raynaud's?'

Over the past 30 years our knowledge of the underlying mechanisms behind the conditions has improved. However, further research is paramount to learning more about the contributing mechanisms and factors at play.

Uncovering the fundamental causes of Scleroderma and Raynaud's will offer immeasurable benefit, by furthering understanding of potential risk factors and allowing for the development and refinement of therapeutic strategies, as well as developing our understanding of whether a person is at heightened risk of experiencing more severe forms of these conditions(s).

Although it is understood that certain factors may make both conditions worse, the questions of what initiates the immune system to attack the body and what makes certain people hypersensitive to the cold or stress remain unanswered. The broad spectrum of Scleroderma and Raynaud's suggests that there are multiple factors contributing to the development of these conditions and their severity, rather than a single gene.

By defining it as one of our core research areas for the next five years, SRUK are committed to ensuring this topic receives more attention and sustained investment.

Our ambitions:

- Increase attention and investment into the causative factors and biology of Scleroderma and Raynaud's.
- Work to provide the research infrastructure in this area, including resources such as patient data and biosamples.
- Work to expand our research community in this area.

Mat's Story

Mat was diagnosed with systemic sclerosis when he was just nine years old. Systemic sclerosis is extremely rare in children; in the UK only 250 children are thought to be living with this condition. Growing up with Scleroderma, Mat began an ongoing battle with chronic fatigue. This meant he had to cut his school week down to four days and was unable to socialise and participate in the activities that most children take for granted.

Now in his 20s, Mat is determined to understand what triggered the onset of

his Scleroderma and Raynaud's at such a young age; environmental and/or physiological factors.

The fatigue caused by Mat's Scleroderma is a major symptom which he must account for in every decision he makes. Deepening our knowledge of the causative factors and mechanisms of both Scleroderma and Raynaud's will help in the development of effective treatments and diagnostic tests and give management techniques to those living with these conditions.

“

Scleroderma and Raynaud's has limited my childhood and teenage years. The only way to find a cure and give those suffering and newly diagnosed hope for a better future is through dedicated research.

Mat

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Michael and Alison's Story

Michael experiences with Raynaud's began in 2002, when his ulcerated fingers meant that even getting dressed became a challenge. Fast forward to today, and Michael now lives with multiple conditions, including limited cutaneous Scleroderma, Sjogren's syndrome, calcinosis and gastric antral vascular ectasia (GAVE).

The symptoms from these conditions have been life-changing for Michael and his wife Alison. Michael had to step back from his career and was forced to sell his business, now eats a highly restrictive diet and is largely dependent on parenteral nutrition. He regularly takes up to eight different medications to manage his conditions. This degree of medical management has also impacted Alison, as life's simple pleasures such as holidays and participating in hobbies are now no longer straightforward.

“

Scleroderma has negatively affected the quality of our lives creating a barrier to many activities we enjoyed as a couple. An incredible amount of organisation and determination is required to allow us to do things we once took for granted.

Michael and Alison

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Quality of life

The research carried out over the past 30 years has contributed considerably to increasing survival rates of those living with Scleroderma. But increased survival can be meaningless if accompanied by debilitating illness and poor quality of life. Many of our community have described the profound impact that living with Scleroderma and Raynaud's has had on their physical and mental wellbeing, affecting both their independence and their ability to enjoy everyday activities. Despite this, quality of life is often unacknowledged when considering the impact of chronic conditions. In fact, quality of life can suffer along each step of the patient journey and is interconnected with other SRUK priority areas: causes, early detection and precision medicine.

SRUK has supported some research in this area such as the innovative finding that the loss of bowel control, often reported in Scleroderma, could be treated through a 12-week course of stimulating certain nerves in the legs with electric pulses. This is now being considered by the NHS as part of routine management strategies. However, the inspiring stories from our community tell us that more can be done in this area.

Our ambitions:

- Fund research on possible treatments and interventions which could improve quality of life.
- Facilitate the development of new and more effective 'outcome measures' which include quality of life and advocate for the use of these in clinical trials, in order to progress treatments with fewer side effects through to the clinic.
- Allow clinicians and patients to have access to existing multidisciplinary resources and non-pharmacological interventions such as physical exercise.
- Enable a cultural shift within the healthcare system by providing an evidence-based foundation that demonstrates the importance of improved quality of life for Scleroderma and Raynaud's patients.

HOW WE WILL REALISE OUR AMBITIONS

To achieve our ambitions, we believe there is an opportunity for us to do things differently and to be more entrepreneurial in our approach. We want to invest in opportunities that will accelerate the progress from bench to bedside for the benefit of patients, rather than be a passive funder of research.

To achieve this, we will:

Build a strong foundation for research

- Develop datasets to assist research into Scleroderma and Raynaud's.
- Facilitate research into biomarkers.

Leverage external investment

- Work to encourage major institutions to fund and support research into Scleroderma and Raynaud's.

Form partnerships to drive innovation

- Collaborate with other funders to promote joint grant calls to maximise the impact of our funding.
- Lead our own research projects, working with innovative partners to advance the aims of our research strategy.

Build research capacity

- Continue to invest in peer reviewed grant funding to ensure that SRUK supports the best quality research.
- Grow the UK Scleroderma and Raynaud's research community and invest in training the next generation of researchers.
- Boost funding for multi-disciplinary research to generate innovative research ideas.

Seek a return on investment

- Ensure that any SRUK funded intellectual property is protected and used in a way which will lead to patient benefit, delivering a return which can be re-invested in research.

Empower patients

- We will support patients to advocate for themselves, and for SRUK. They will be supported through inclusion in research, conducted by both SRUK and the research teams we fund.

OUR COMMITMENTS TO OUR COMMUNITIES

Medical research is important, but also costly. At SRUK we are committed to maximising efficiency and impact within our research spend.

Dissemination of Research

Research is often an incremental process; new scientific ideas are disseminated, studied and built upon by others. To facilitate research dissemination, SRUK has signed up to the Association of Medical Research Charities (AMRC) OpenResearch platform. Our research community will be able to publish their work promptly on a platform accessible to all, including our patient community, at a reduced cost. This will allow for greater reach and contribute to a faster translation of key research findings.

We aim to work effectively with researchers and their organisations, ensuring any significant advances are communicated effectively to our community.

Impact and Evaluation

We will regularly evaluate our performance against our research objectives and the outcomes of any activities we undertake, in relation to the Research Strategy's four themes, to ascertain what is proving beneficial and effective, and whether any improvements can be made. Evaluation will be made against the following criteria:

- Building a strong foundation for research.
- Promoting collaboration between academia and industry, ensuring that continuous research on Scleroderma and Raynaud's is supported.
- Producing a return on investment, in terms of both financial return and patient benefit.

Accountability

We are grateful for the generous donations we receive from our dynamic community and we will continue to ensure that these donations are responsibly invested in research. We are a member of the AMRC and adhere to their research governance guidelines for commissioning and monitoring research. We will inform our community of our funding decisions and ensure projects are monitored closely enabling us to keep the community up to date with SRUK funded research.

Inclusive

We aspire to involve people living with Scleroderma and/or Raynaud's within our research funding decisions. We will endeavour to create an environment and develop best practice to achieve this goal.

BE PART OF THIS EXCITING NEW CHAPTER IN SCLERODERMA AND RAYNAUD'S RESEARCH.

Become a Research Investor and be at the forefront of advances in knowledge, treatments, quality of life and get us closer to the ultimate goal - a cure.

As a research investor we will keep you updated with the latest news in research; when we make breakthroughs you will be amongst the first to know about it.

Find out more



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