



*societì*  
The UK Foundation for Kawasaki Disease

*Societi Foundation  
Patient and Public Involvement  
KD-CAAP Clinical Trial*

*March 2025*



If a child has a **PERSISTENT FEVER**  
and two or more of these symptoms  
**THINK KAWASAKI DISEASE!**



Persistent fever



Cracked lips/  
'strawberry' tongue



Rash



Swollen fingers/  
toes



Bloodshot eyes



Swollen glands

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# societi Kawasaki Disease: #1 cause of acquired heart disease in children, in Europe

## Foreword

### A word from our Founder

I'm Rachael McCormack, Founder of Societi and a parent of a child who had Kawasaki Disease. I brought a team of doctors together in May 2016 and asked them what would make the most difference to outcomes for children affected by Kawasaki Disease. Unanimously, they said, better acute treatments.

The rest, as they say, is history! From that point we worked together to develop a ground-breaking clinical trial, informed by families at every stage.

The KD-CAAP clinical trial was potentially the single BIGGEST opportunity in a generation to make a difference for children affected by Kawasaki Disease. It's a pioneering trial, connecting communities of brilliant doctors from across the UK and Europe – using their shared knowledge and experience to truly help our children – and protect their hearts.

We just must have better treatments, for children who are affected by Kawasaki Disease – it's the leading cause of acquired heart disease in children and we really want to change this.

I find it shocking that 39% of babies under 1 year in the UK with Kawasaki Disease go on to develop life threatening heart damage with current treatments – and 1 in 5 of all children who have Kawasaki Disease will need care for life, as they are left with serious heart damage – even if they get the standard medicines on offer. Similar, terrible harm is happening to children across Europe who have Kawasaki Disease and KD-CAAP had the potential to help change this. We are determined to stop this devastating impact on so many children – finding new treatments is really urgent.

I'm so very (very!) glad KD-CAAP got up and running, and that so many wonderful families have chosen to take part. They received excellent care and close monitoring from doctors who really know Kawasaki Disease – as well as playing a very important part in protecting children's hearts in the future!

I wish we'd had the opportunity to take part in such an amazing trial when my daughter had Kawasaki Disease. I'm very proud that, through our close work with the doctors leading the trial, the experience that families who take part will have has been carefully shaped by families, who have been through Kawasaki Disease themselves.

Throughout this document there's more information on how KD-CAAP began and lots more on Kawasaki Disease – setting the scene for why this research was so crucial, and so very urgent. There's much more on many aspects of our PPI work too.

I am deeply grateful to the extraordinary and determined team of talented doctors and other healthcare professionals whose persistence and hard work has ensured this clinical trial advanced, from an ambitious concept to an innovative trial. And I am immensely grateful to our equally ambitious funder, Conect4Children, who saw the enormous potential of our trial to make a transformational impact for our children, wherever they are across Europe.

**I know I can extend the thanks of everyone in our community for the work that has been done and the investment made – to protect our children's hearts.**

**We are in your debt.**

*Rachael McCormack*

**Rachael McCormack, Founder**

# societi Kawasaki Disease – key facts

## Where we are today

**28%** of affected children with heart damage

**39%** of infants develop coronary artery aneurysms

**8** day average treatment time  
Too slow!

**Inconsistent** care for children

Partial UK coordination knowledge pockets, poor general awareness

## Where we need to be

**4%** (or less) of affected children with heart damage

**dramatic reduction** in infants developing coronary artery aneurysms

**5** day average treatment time

**Consistent** care for children

UK-wide coordination high levels of awareness, strong partnerships



**Kawasaki Disease is the leading cause of acquired heart disease in UK children**



Across the globe, incidence of **Kawasaki Disease** has doubled in the last decade. In the UK, hospital admissions have increased **FOURFOLD** in the same period

Awareness of **Kawasaki Disease** is low

**39%** of treated infants develop coronary artery aneurysms  
**28%** of all treated children will suffer some heart damage  
**19%** of treated children overall develop coronary artery aneurysms

More UK children today are diagnosed with **Kawasaki Disease** than some forms of bacterial meningitis



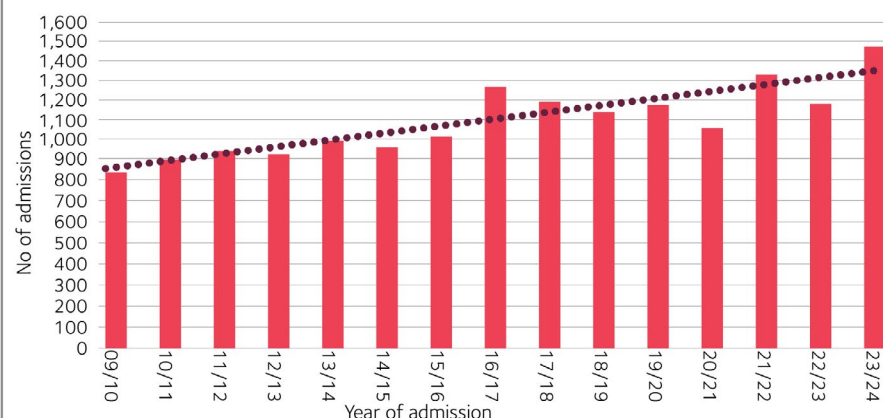
**Delayed treatment = increased heart damage**



An estimated **20,000** children and young people in the UK are affected by **Kawasaki Disease** today

## Kawasaki Disease UK hospital admissions 2009/10 – 2023/24

■ Kawasaki Disease hospital admissions\*



\* NHS England HES data – Kawasaki Disease hospital admission episodes with 11% uplift to include for rest of UK based on population



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## It's urgent: Changing outcomes for our children

### What difference can Societi make?

#### Our aims

We are an influencing and policy shaping organisation, always working through partnerships to achieve our aims.

Societi has four aims:



**1. Awareness raising** – a voice for Kawasaki Disease



**2. Clinical research** – sharing knowledge, influencing funders and enabling co-ordination



**3. Clinical supervision** – shaping new care protocols and health policy



**4. Support for UK families** – enabling a sustained focus on family support

#### Responding to urgent need

An evidence-led approach to our work is a characteristic feature of Societi Foundation – with even our earliest strategic priorities being shaped by known need. As we have grown, we have undertaken and been informed by more research and this continues to underpin our areas of focus.

Key findings include incidence patterns and outcomes for children, as well as family feedback on their experiences. This has also highlighted that more investment in research is needed, including investment in clinical trials.

Particular research on which we have drawn includes a landmark study from the British Paediatric Surveillance Unit (BPSU), *Kawasaki disease: a prospective population survey in the UK and Ireland from 2013 to 2015*, our own studies in 2016, 2019 & 2023 on hospital admissions for every NHS trust and health board in the UK and in 2024 our work with NHS England looking at HES admissions data. These studies highlight key challenges for children affected by Kawasaki Disease including:



Early treatment is critical



Kawasaki Disease is rapidly on the rise



19% CAA  
19% of children will develop coronary artery aneurysms (UK & Ireland data)



28%  
28% of children will suffer heart damage



<1 CAA 39%  
39% of infants will develop coronary artery aneurysms



47%  
47% of children will not show all symptoms



Significant over representation of Kawasaki Disease in those of ethnic backgrounds



Kawasaki Disease is seen slightly more often in boys than girls



↑  
Rurality  
Higher incidence in children from rural areas



365  
Cases of Kawasaki Disease are broadly constant all year round



>5 20%  
1 in 5 affected by Kawasaki Disease are over 5 years old



<1 1/3  
1 in 3 Kawasaki Disease patients are younger than 1 year old

#### Action will change outcomes

Kawasaki Disease is a serious illness, but today it is little known. With around 1,000 UK children affected by Kawasaki Disease every year, almost a third will suffer some heart damage. Around 1 in 5 children affected will suffer severe heart damage, developing lasting coronary artery

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## Actions we need: including a clinical trial for better treatments – KD-CAAP

aneurysms, putting them at heightened risk of a major cardiac event and sudden death in later life. Up to 3% of children, every year, may die from untreated acute Kawasaki Disease. If all children received timely treatment for Kawasaki Disease, **many children could be saved from a lifetime of heart damage.**

Even with treatment, too many children go on to develop lifelong heart disease and we must change this. **Better treatments for acute Kawasaki Disease are needed urgently and we're pleased to support the KD-CAAP trial**, researching the effectiveness of a possible adjunctive medicine – corticosteroids. Later, this document describes our involvement in more detail.

Kawasaki Disease hospital admissions in the UK are increasing year on year. With a 3 to 4 fold increase in the over the last decade alone, increasing incidence will only serve to push these numbers higher – so our work is truly urgent. More common than bacterial meningitis, too few doctors and too few parents know Kawasaki Disease. Yet, just like meningitis – it is a medical emergency.

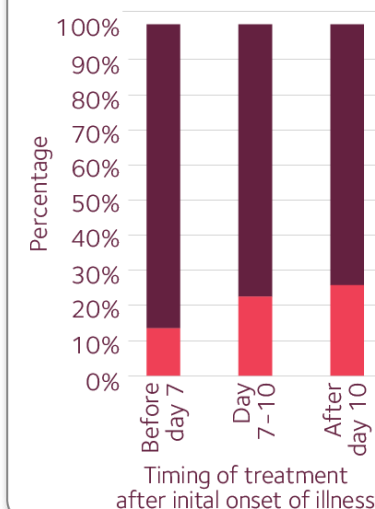
Research shows that **rapid diagnosis and treatment greatly reduces the risk of heart damage in children.**

A study by the BPSU helped us understand how treatment times in Kawasaki Disease can affect outcomes for children. The graph opposite shows the relationship between the number of days to treatment, from illness onset, and the rate of heart damage. The treatment referred to in the graph is aspirin and intravenous immunoglobulin.

Despite current treatment, 28% of all children affected by Kawasaki Disease will suffer some form of heart damage and today, **there are an estimated 20,000 children, young people and adults living in the UK with the effects of Kawasaki Disease.** With no registry currently available, there is no accessible, definitive data on these patients and no way to inform them of updates or advances in patient care.

### Association of treatment timing with coronary artery aneurysms (CAA)

Percentage of Kawasaki Disease cases resulting in CAA  
Percentage of Kawasaki Disease cases resulting in no CAA



**Societi Foundation is working every day to improve the outcomes and improve lives for everyone affected by Kawasaki Disease in the UK.**

It is essential that we continue to raise awareness of Kawasaki Disease with the general public as well as with GPs, emergency medicine doctors and paediatricians.

We know **that working with powerful partners is the only way we will achieve our goals with pace, and protect thousands of tiny hearts** from the devastation that Kawasaki Disease all-too-often causes.

## *societi* **KD-CAAP: Shaped by families, for families, affected by Kawasaki Disease**

### **KD-CAAP: a patient-led origin**

#### **Our clinical trial**

The Kawasaki Disease Coronary Artery Aneurysm Prevention trial, or KD-CAAP, was a clinical trial designed by doctors to see if we can find a better treatment for Kawasaki Disease in children.

With standard treatments, children with Kawasaki Disease currently have a very high risk of lifetime heart damage. Standard treatments just aren't that good and there's been no change in the medicines given for Kawasaki Disease in decades. So, we were excited that at last, through this important trial, doctors started working to find better treatments which might help more children recover from Kawasaki Disease without serious heart damage. KD-CAAP was "a phase III multi-centre, randomised, open-label, blinded endpoint assessed, trial of corticosteroids plus intravenous immunoglobulin (IVIG) and aspirin, versus IVIG and aspirin for prevention of coronary artery aneurysms (CAA) in Kawasaki Disease (KD)".

#### **A novel beginning for KD-CAAP**

A parent, whose child had Kawasaki Disease as a baby, established Societi Foundation, in 2015. She wanted to create an organisation with information and support for families affected by Kawasaki Disease. When her family had been affected by it, she'd found nothing she could rely on or trust. She was also concerned that there was no focus for action on Kawasaki Disease in the UK.

In May 2016, just a few months after starting the charity, she brought the leading doctors in the UK with expertise in Kawasaki Disease together, and asked them – **"If we did one thing to help children affected by Kawasaki Disease most, what would it be?"**

The doctors unanimously said **"We urgently need to find better treatments for children who have Kawasaki Disease and prevent so many children having serious, life long heart problems."**

Reflecting on this start, this was a novel approach to identifying clinical need – as it was parent led. Whilst the benefits of involving patients and parents in trial design is well understood, this

approach went further and it was the parent who catalysed the initial discussion on research needs.

From that first meeting, work began to design a trial (now known as KD-CAAP) to add an extra medicine (a steroid) to the usual treatment for Kawasaki Disease, to find out if this could reduce heart damage.

The work was detailed, and took several years to design the trial and find a funder who was interested in investing in this very important research.

#### **Designing KD-CAAP: families at its heart**

Right at the heart of trial design were families. At the very start, we brought families together who had been affected by Kawasaki Disease, and had themselves been through the treatments, hospitalisation, follow up visits and more – and we asked them **"Help us to design this trial. Use your experience caring for your poorly child through Kawasaki Disease to help us decide on how we shape the trial, what tests we use and how the children can best be looked after during and after their stay in hospital."**

Our families, including children, with specially designed workshop activities, worked with us to decide on things like the number of blood tests which might be acceptable, and the length of time after discharge from hospital that it would be OK to keep seeing the doctor for check ups.

#### **Families choose extra checks, extra care**

Without exception, ALL our families felt that they would have been reassured by a few extra tests and checks, from experienced doctors who really knew Kawasaki Disease, if they'd been invited to take part in a trial. They said they'd have chosen the trial rather than standard treatment alone, because of this really valuable extra support – whether or not they got the extra medicine the trial is looking to test. Families also told us, without exception, that **having very close monitoring of their child's health because they were part of a clinical trial, with the option of additional treatments if their child was unwell, would be a huge benefit** of taking part in a trial. That feedback really helped our doctors as they planned the trial.

## *societi* **KD-CAAP: A once in a generation opportunity to improve outcomes**

### **Societi's role in KD-CAAP: the beginning, the middle and the end**

#### **Involved at the beginning**

The concept for KD-CAAP emerged following a meeting in May 2016, at the Institute of Child Health, London. The meeting was called by Rachael McCormack, Founder of our then newly established charity. Rachael had invited leading doctors to meet and discuss the research priorities for Kawasaki Disease, keen to mobilise a research project of sufficient scale and impact that it would make material and beneficial change for those children affected by Kawasaki Disease.

As we've described, we were the catalyst for the trial concept, which was then rapidly developed by a team of brilliant doctors and clinical trial experts, and we stayed involved in trial planning and design. Ensuring families were involved was a key work area for us too – so that they could help shape it.

#### **Involved in the middle**

We were a co-investigator in the trial, and had responsibility for patient and public involvement (PPI) throughout the trial period.

Our work areas included:

1. Co-ordination of the patient/public involvement programme
2. Technical/administrative input (linked to key areas)
3. Senior lead PPI – leadership and overview
4. Collateral – design, development
5. Information distribution, evaluation & feedback
6. Website
7. Information management (related to PPI)
8. Group work
9. Participant and centre updates

Our PPI work has been varied and complements the charitable objectives of our organisation, so we have been able to amplify our work in support of KD-CAAP – because in areas like raising awareness of Kawasaki Disease, supporting families affected and providing accurate information to doctors, these are both our PPI goals and our charitable purposes.

We worked to raise awareness of the trial (and Kawasaki Disease) throughout the project and we worked to provide the information families needed as they considered joining the trial. We provided the information they needed before, during and after their active involvement in the trial.

More details on Societi Foundation's PPI activities are included on the following pages, and all the resources we created have been both distributed widely, and were freely available to families and their clinicians.

#### **Involved at the end**

Our involvement hasn't stopped now that the clinical trial has come to an end.

It is so important to us that we share every finding from this uniquely significant clinical trial, from its achievement of strategic goals to build powerful paediatric partnerships across Europe which can rapidly drive forward solutions in children's health, to the effectiveness of the trialled treatment.

With so much having been invested by so many partners in this clinical trial, including our families who gave their time and energy from the very start, we must share all we learn, and make sure that this trial goes on to make a difference, whatever the findings.

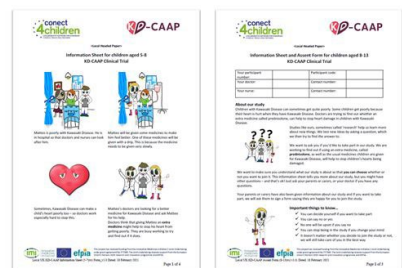
We will be involved in dissemination, and trial outcome findings promotion. We will make sure that families across our Kawasaki Disease community and far beyond have access to trial findings in easy to digest, easy to understand materials – and in the ways that suit them best.

#### **An approach with wider application**

The innovative approach taken to establish this trial has brought benefits to the trial team, including deep family involvement making it highly attractive to the funder and many benefits for participating families who have been able to access a wide range of support both during and after the trial. Potentially transferable, the methods used within the KD-CAAP trial are applicable across children's health research.

# societi KD-CAAP: Engaging, communicating and supporting our families

## Our work during the KD-CAAP trial



### 1. Patient and family forms

Societi worked with the clinical trial team to develop a suite of KD-CAAP information leaflets, consent and assent forms, which are age specific and use images as well as carefully selected language to both appeal to and be understood by the different age and developmentally specific patient groups they are designed for.

This suite of forms was kept under review during the trial, and feedback was sought from centres when the forms were in active use in recruiting sites.

### 2. Family information booklet

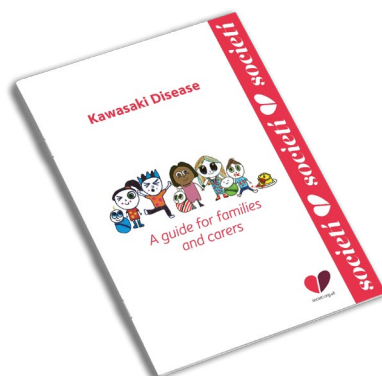
Work was completed on a significant project, involving a team of families and clinicians, to develop a printed family and carers booklet. This is now being made available to families whose children are in hospital, following a Kawasaki Disease diagnosis. The booklet, as well as being available through usual channels such as our website, was directly distributed to all KD-CAAP trial centres, to provide information and help support families affected by Kawasaki Disease.

The response from families to the booklet has been terrific: **'The mention of heart damage from the doctors when our son was ill was something we found very overwhelming, but the 'complications' and the 'coronary aneurysm' sections and the explanations and the images used in the booklet are so helpful, clear and reassuring'.**

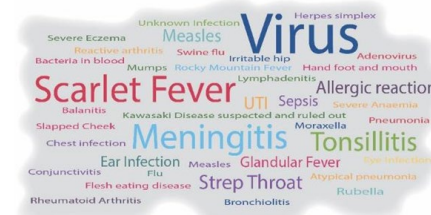
Families said: **"It's just great to have all this clear, supportive information in one place."** **"So grateful for the care that's been put in to help us understand what's happened."** **"At a scary time, this is just what we needed, thank you."**

### 3. Newsletters and social media

A dedicated KD-CAAP trial newsletter which Societi input into, was complemented by our main charity newsletters throughout the trial period which included updates to our wide community of supporters, on progress with the trial. Dedicated social media materials for the trial were prepared, including a KD-CAAP X account, and Societi social media channels (Twitter, Facebook and LinkedIn) were also used to promote and raise awareness of the work within the trial. That included signposting people to refer to the dedicated website information and contact us for more information on either KD-CAAP, or clinical trials generally.



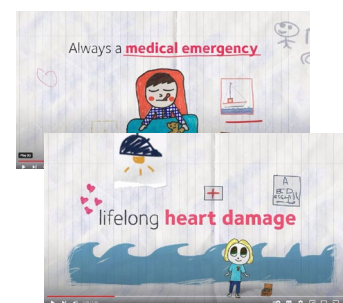
# societi KD-CAAP: Promoting the clinical trial, sharing our work



Societi Foundation Diagnosis Day study, R McCormack et al

### 4. 'Diagnosis day' study

Information from over 200 families affected by Kawasaki Disease has been collected as part of Societi's ongoing Diagnosis Day study, undertaken to help understand experiences of Kawasaki Disease diagnosis. The study aims to provide insight into misdiagnoses that are happening before Kawasaki Disease is correctly diagnosed and what Kawasaki Disease is being confused with. Results of the ongoing study were shared with doctors, including those involved in the KD-CAAP trial, to focus training about the differential diagnoses for Kawasaki Disease, and help overcome problems being faced.

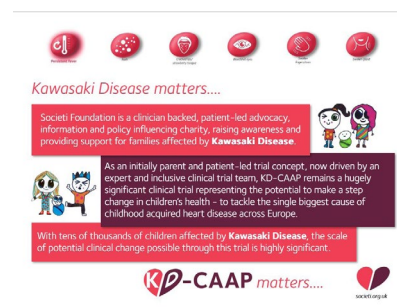


### 5. Awareness Animation

A 90 second animation was created, starring our much-loved Societi Kids, to provide an engaging and practical way to share important Kawasaki Disease information. It has been shared widely across our social media and sent to all KD-CAAP centres, supporters and partners. The video has been extremely well received and we have had very positive feedback.

### 6. Resourcing our PPI work

We dedicated a significant proportion of team capacity to KD-CAAP PPI works, adding value to the core contracted activities undertaken, since the project commenced. This has been made possible with the expansion of the team as well as additional technical, administrative and marketing resources. The additional capacity brought in was in lock step with the acceleration of site openings and recruitment of trial participants, ensuring that we were able to continue to support families, provide clinician information (including parent and patient facing materials) and was an ongoing source of responsive PPI support, for all members of the Clinical Trial team.





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## 7. Clinical centre information

Information and resources were developed by Sociati on an iterative basis throughout the trial and were made available to clinical centres. Materials were for use by doctors involved in the delivery of KD-CAAP. Collateral was developed working with leading experts and remains available online, as downloads and as printed materials.

During the trial, this was kept under review and developed as needed. An example of these developments include the issue of a comprehensive resource pack to each hospital centre across Europe actively engaged in the trial, with further clinician updates throughout the trial period.



*Comprehensive clinical resource pack, led by clinical experts in Kawasaki Disease, prepared by Societi Foundation*

## 8. Parent & patient materials

Patient and family information, parent booklets, newsletters and social media have all contributed to the information parents and patients could access as participants in the KD-CAAP trial. In addition, dedicated resources were developed and kept under review throughout the trial including information leaflets, podcasts, dedicated on-line web-pages and many other materials.

Work was undertaken to provide translated materials (key content) where possible, so that families were able to access materials and information in the way most convenient to them.



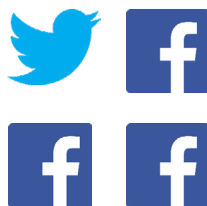
Information leaflets and long-term issues  
leaflets for families and school/nursery  
settings



Parent Portal with multi media family support resources



*"My Societi" online space deigned for and by young people affected by Kawasaki Disease*



*Social media fully utilised*

## society

## 9. Partnering with influencers

In our work to raise awareness of the trial and engage a wide community of interest around Kawasaki Disease, we partnered with businesses, charitable foundations, agencies, institutions and global organisations.

Examples include our work with the World Heart Federation in every campaign throughout the trial period, raising awareness of Kawasaki Disease.

We've worked with international colleges including the Royal College of General Practitioners, and the Royal College of Paediatrics and Child Health, business membership groups like the Chemical Business Association and key supporters, such as the Randal Charitable Foundation. Their support has powered our work to raise awareness of the KD-CAAP trial, and the urgency with which we need to combat Kawasaki Disease.

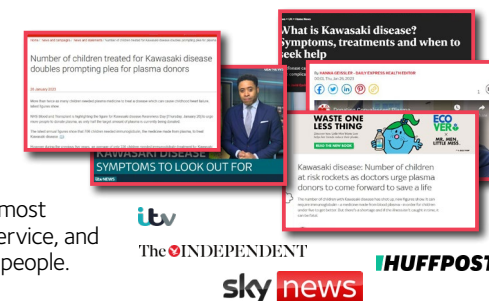
## 10. Media engagement

We believe that engagement with the media is crucially important for children's health generally, and of course, it is essential for Kawasaki Disease awareness.

We worked with partners throughout the clinical trial, to support media releases on Kawasaki Disease - the most recent of which was with NHS Blood and Transplant service, and reached media outlets with a readership of 25 million people.

## 11. Key campaigns

KD-CAAP featured each year in our two annual major campaigns – International Kawasaki Disease Awareness Day and World Heart Day. We joined forces with partners through these campaigns to reach across Europe and globally. We achieved hugely elevated amounts of traffic on our website and across social media including KD-CAAP content, with more people finding out about the trial. Our campaign media statements set out the huge importance of KD-CAAP and urged continued research investment.



Campaign branding and strap-line –  
2022/23

# societi KD-CAAP: Accredited courses and materials for KD-CAAP doctors

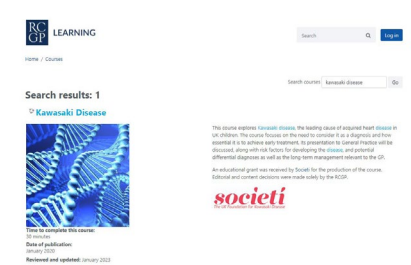
## 12. Training resources

We worked with the RCGP to develop a webinar based CPD certified training course for Kawasaki Disease – a course which was renewed during the trial to ensure it remains available to GPs, paediatricians and anyone with an interest in Kawasaki Disease. Funded by Societi Foundation and developed by leading experts in Kawasaki Disease, this was a key resource to underpin early diagnosis of Kawasaki Disease and help in turn with trial patient recruitment in centres participating.

Societi also created, published and updated a comprehensive, expert clinician-led “Spotting Zebras” booklet to ensure that the most accurate and detailed information was available to clinicians likely to see children with Kawasaki Disease.

We worked with RCPCH to run a “Think Kawasaki Disease” training webinar for paediatricians. It remains the most highly viewed training webinar the college has published.

We worked throughout the trial to promote resources available to doctors which helped them learn more about Kawasaki Disease and have developed a series of training podcasts, including one specifically focussing on KD-CAAP and research needs.



Societi funded and developed training courses on accredited clinical institution platforms



Note: Training resources will remain available beyond the trial period and will be kept up-to-date, if funding can continue to be identified to do so. We will actively search for funding for this as these are valuable resources for healthcare professionals who see children.

## 13. Website

Website content for dedicated KD-CAAP trial pages were created and underwent a process of continual review, being added to over time. Additions included new information, addressing queries and FAQ's as they were identified. Input and feedback was actively sought from the clinical trial team and was also sought from our community of users accessing the web-pages.

A process of periodic review and update was in place, including updating information on centres, status, openings and recruitment, which ensured the online information was kept current.



# societi KD-CAAP: Families and patients, support and diverse participation

## 14. Patient and parent liaison

Following considerable in-person engagement at the concept and early development stages of the trial, with the arrival of Covid-19 and restrictions on movement and gatherings, all Societi's group work moved to virtual delivery instead of in-person events. The latter were either not possible or not desired by families. Work with our families therefore continued and also involved feedback to families and young people involved at the design stage, on the development of specific resources. Topics we engaged our families around included (not exhaustively) age appropriate consent and assent information bespoke to the trial, website development (KD-CAAP clinical trial pages), trial design considerations – including those which arose when new jurisdictions progressed through their approvals processes, our diagnosis day study, and our family and carers booklet where a virtual working group of families came together to help create a valuable resource for affected families. This was informed also by

the views of over 50 families, who responded to our survey to find out what information would help parents most, after a diagnosis with Kawasaki Disease.

Family / parent podcasts were also developed throughout the trial period, allowing families to share their experiences of Kawasaki Disease with other families facing this most difficult challenge.

Newly affected families are in need of support and information, and the voice of parents who have been through a Kawasaki Disease journey, they tell us, is one of the most reassuring things to hear.

We developed our family stories as transcripts too – and an additional four family journeys were developed as animated films, during the trial period.

We maintained ongoing dialogue with our families about KD-CAAP through our social media groups – and connected with all those interested in finding out more about the trial.



Left: Extract from one of a series of new family podcasts developed to support families facing Kawasaki Disease

Below: Extract from our family and carers guide to Kawasaki Disease, acknowledging the wonderful support of many parents in developing the guide



A huge thank you to our wonderful families who helped develop and review this booklet, especially Sammi, Laura, Lisa, Joanna, Jess, Sue and Suzanna.



## societi *KD-CAAP: Family voices, sharing their journeys and supporting more families*

### 15. Family films

Within the trial period, work was undertaken to refresh our family films offer.

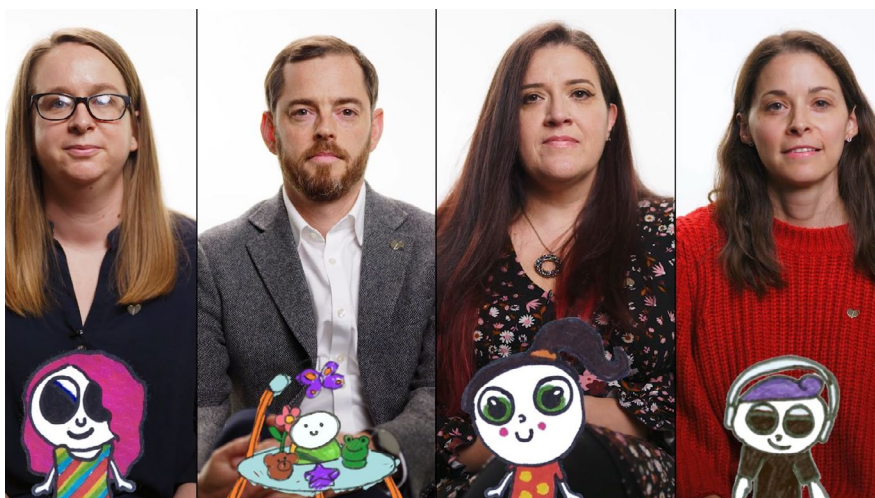
These new family films were released on 26 January 2023 – International Kawasaki Disease Awareness Day! The creation of the films was a huge success and we are very grateful to the families who so generously gave their time to help others affected by Kawasaki Disease.

The films have provided families affected by Kawasaki Disease with valuable advice and information directly from those who have been in similar situations. The films allow a virtual connection between affected families – it's a virtual hug in fact, when families know they are not facing Kawasaki Disease alone. These resources were considered to be of particular importance to families involved in the clinical trial – who may feel an even greater need to make a link with others who have been through this challenging, distressing and worrying time.

The films remain available to view on our family portal and have been (and continue to be) shared widely across our social media platforms.

Importantly, the films tell the stories of how deeply families are affected by Kawasaki Disease, sentiments which it has been essential for us to convey to all the doctors involved in the KD-CAAP trial. This is to ensure they have the fullest and most direct understanding of the devastating impact this disease can have, from a family perspective.

As well as supporting families by providing much needed and trusted Kawasaki Disease information, a summary film which captures all four family stories in less than 4 minutes was made available to clinicians, to share important insights about the experience families go through. The films are free to use at any time and are available on the Societi website [www.societi.org.uk](http://www.societi.org.uk).



Societi funded family films, supporting patients and their families

## societi *KD-CAAP: Expert-led training, looking to the future of Kawasaki Disease care*

### 16. Kawasaki Disease acute management: An expert-led discussion

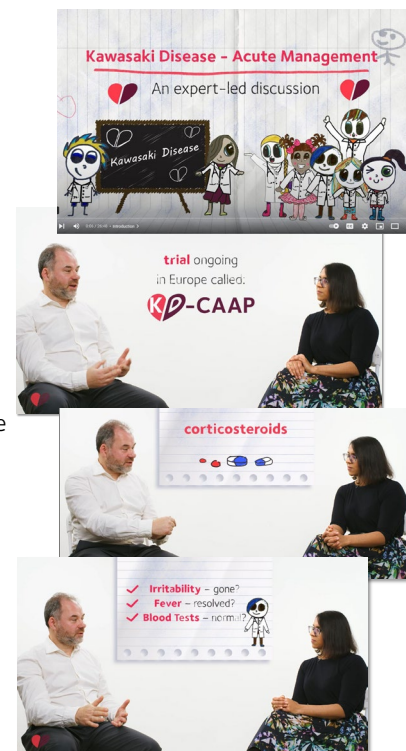
Societi created and released a 25 minute clinician training film on Kawasaki Disease acute management. Led by a leading expert in this field, Dr Jethro Herberg – Consultant Paediatrician and Clinical Reader in Paediatric Infectious Diseases (who sits on the Societi Foundation Advisory Board) and Dr Harsita Patel – Paediatric Trainee. Both are based at the globally recognised centre of excellence in children's medicine – Imperial College London.

The structure of the film was guided by Professor Paul Brogan and Professor Despina Eleftheriou, who led the KD-CAAP clinical trial.

The training film features discussion on KD-CAAP and its work to explore adjunctive treatments for Kawasaki Disease to reduce heart damage in affected children.

The training film was launched in January 2023 and was shared widely including across all KD-CAAP centres.

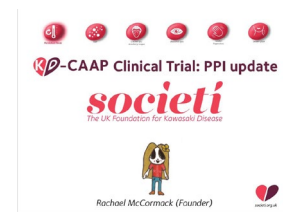
This hugely valuable clinician film is also available as a podcasts and a transcript, to be shared on the Societi website and shared on social media.



### 17. Reporting

Societi colleagues were active members of all relevant trial information, management and steering groups and were included across all aspects from the outset.

We reported at each meeting on progress against planned work targets and discussed impact, as well as offering support to the wider trial team on any matters which may have benefited from a PPI focus or perspective.



## Our people



**Rachael**, our Founder, is an energetic and dynamic leadership professional with wide ranging executive experience across public and private sector organisations. She is recognised for a focus on enabling high impact, delivery through partnership, achievement of outcomes and a leadership approach which is collaborative and decisive.



**Rob**, MA DM FRCPCH Honorary Professor of Congenital Cardiology and pulmonary hypertension, is an internationally recognised expert in Kawasaki Disease. Rob led the largest Kawasaki Disease clinic in the UK and the only Adult Kawasaki Disease clinic. He supported Societi before its formal establishment and chairs our Trustee Board, providing strategic oversight for our organisation.

## Our Trustee Board

Our five Trustee Board Members, Prof Robert Tulloh (Chair), Rachael McCormack, Prof Paul Brogan, Mr Roger Greenwood and Prof Mike Danson, bring together a strong combination of skills and expertise to drive and direct the work of our charity.

# Teamsocieti

## Team Societi

TeamSocieti is a simply amazing network of over 5,000 Societi supporters. Every single member of TeamSocieti is dedicated to improving awareness and care for those affected by Kawasaki Disease across the UK and shares the core values of Societi Foundation. Volunteer fundraisers and awareness raisers across the UK help guide, shape and inform our work. TeamSocieti fundraising accounts for over 70% of all of Societi Foundation's income. It is vital that we continue to support TeamSocieti and build on their strengths, determination and extensive reach to achieve our common goals.

## Scientific Advisory Board

Kawasaki Disease has many effects on a child and a multi-disciplinary approach to research/care is needed. Societi is supported by the phenomenal clinical expertise of:

**Prof Despina Eleftheriou**; Great Ormond Street Hospital and Institute of Child Health

**Prof Paul Brogan**; Great Ormond Street Hospital and Institute of Child Health

**Prof Michael Levin**; Imperial College London

**Prof Tom Johnson**; Bristol Heart Institute

**Prof Damian Roland**; University Hospitals, Leicester

**Dr Owen Miller**; Evelina London Children's Hospital

**Dr Filip Kucera**; Great Ormond Street Hospital

**Prof Jethro Herberg**; The Royal Brompton Hospital

**Prof Ifeanyichukwu Okike**; Nottingham University School of Medicine

## UK Kawasaki Disease Steering Group

The UK Kawasaki Disease Steering Group comprises national leaders and influencers from key organisations who together act as a catalyst for positive change:

**Societi Foundation** – Chair  
**Societi Scientific Advisory Board** – including clinicians from Great Ormond Street, Bristol Heart Institute, University Hospital Leicester, Imperial College London, Royal Brompton Hospital London & Evelina London Children's Hospital

**NHS England** – National Clinical Directors – for Children, Young People and for Heart Disease

**BCA** – Representative

**UK Health Security Agency** – Representative

## Key partnerships in place

We are not standing still in the face of our challenges. We recognise that we cannot overcome the huge obstacle that Kawasaki Disease represents, without powerful partners standing with us. So, each week we forge new relationships, expand our networks, promote key messages through social media and raise the profile of Kawasaki Disease in all we do. Today, we are;

- PPI lead and partner to **UCL Hospitals Trust** in a multi-site, pan-European clinical trial, **KD-CAAP** for acute Kawasaki Disease treatment funded by **Conect4Children**. Societi leads work with families and creates patient information/clinical resources.
- working in partnership with **The Randal Charitable Foundation** who have generously funded our Children's Hospital Partnership Programme growing knowledge with clinicians and ensuring improved care for affected children.
- PPI lead for a national surveillance study for PIMS-TS, led by the **British Paediatric Surveillance Unit** and our work includes promoting this to clinicians and affected families.
- working actively with **NHSBT** promoting plasma donation and **NHS England** through our UK Steering Group for Kawasaki Disease.
- raising awareness and supporting high impact visibility campaigns for Kawasaki Disease with

**Clear Channel UK**, a global leader in outdoor advertising.

- promoting our E-learning module created in partnership with **RCGP** for Kawasaki Disease which is CPD accredited by the **RCPCH**.
- in dialogue with the **BPSU and RCPCH** working together on a range of projects to raise awareness with the paediatric medical community.
- collaborating with **sister organisations** in Australia, Canada, Italy and Spain. Our organisations have a shared commitment in the fight against Kawasaki Disease across the globe.
- working with the **World Heart Federation** through social media to bring global awareness to Kawasaki Disease.
- partnering through our Scientific Advisory Board with **Bristol Heart Institute, University Hospitals Leicester, Great Ormond Street Hospital, Evelina London Children's Hospital, Royal Brompton Hospital, London and St Mary's Hospital London**.
- In dialogue with dozens of MPs, in meetings and attending **Westminster**, with **Lexington Communications** to discuss the need for a patient registry and public investment to address the increasing incidence of Kawasaki Disease.



## Valuing PPI in the clinical trial context

### PPI is undervalued

As we've noted earlier in this paper, the challenges around Kawasaki Disease are immense in scale and diverse in nature. When approaching how best we could support KD-CAAP, we expected it was unlikely that a funder would wish to consider the whole cost of PPI activities which we assessed as needed, to fully support the project. Even when recognising that only a very small proportion of the total trial costs would be allocated to PPI, we understand that this continues to be an activity area which is currently widely undervalued and under-recognised when funders seek to invest in clinical trials, when clinical trials are planned and when trial budgets are built.

### Establishing a basis on which to work

In the face of this obstacle we were not deterred – as the KD-CAAP trial was of such great importance to our community and our charitable goals – including ensuring children promptly receive the very best treatment available, and fewer children suffer the all-too-often devastating impact of heart damage, from Kawasaki Disease.

Having proposed an inclusive budget for PPI delivery, this was rejected based on costs being too high. A revised proposal was developed, for which the average cost per year, over 4 years, was less than £34,000. This is less than the cost of a research nurse over this period, and circa 3% of the total trial funded cost. This became our contracted budget for what we believe to be the uniquely important elements of patient and family participation, from concept to dissemination and family support infrastructure throughout the trial.

This reduced budget did not reflect the whole costs of PPI activity, as we proposed to deliver it. Our aim was to add deep value to the process, positively and proactively shaping all aspects of the trial wherever this was practically / usefully possible. This includes from the outset with the trial concept and

design, to supporting centres and adding value to the experience our participating families have, supported with excellent information and recovery resources.

### Leveraging our resources

We have, we believe, achieved this goal, but only thanks to the trial team who established as high a budget for our delivery as they felt they possibly could, exceeding that often provided for 'similar' PPI inputs in clinical trials, and by fully leveraging the networks and resources of our charity – so that we can properly and professionally deliver a comprehensive contribution as the PPI lead for this Europe-wide trial. We have sought from the outset to provide PPI specialist input for all aspects of the trial, whilst keeping our families in focus – and providing them with all they need as they move through their most difficult and worrying journey with Kawasaki Disease.

### Our impact

Societi Foundation has adopted a 'theory of change' model to help understand the impact we have through our activities, as we delivered against our strategic priorities. It identifies a range of possible areas in which data could be collected and targets for action, to accelerate the achievement of impact which was described.

The theory of change model was popularised in the 1990's as a way of demonstrating impact for organisations or programmes that are more complex, with direct and indirect areas of influence which effect cumulative change, and are as such very difficult to measure. Our model showed *individual, communities of interest and collective actions* as the three areas from which our change and impact results. Our communities of interest include researchers and our team for the KD-CAAP clinical trial.

### Quantifying aspects of our work

- Mindful of the context that the KD-CAAP budget for our PPI works did not support the full extent of PPI delivery undertaken,

we were asked to provide further information on four localised areas of our involvement **over the four year period** of the trial:

1. Patient representative workshop
2. Participation in the TSC
3. Creation of a Patient Advisory Mechanism
4. Development of brochures/educational materials

### Patient representative workshop:

Described on page 8 of this paper, this was a design stage workshop to gather patient feedback and directly inform protocol design/ review concepts. It took place in 2017, long before funding had been secured and the costs for Societi input was fully met by our charity. In addition, families were reimbursed for their travel directly by UCL. An estimate of time taken can only be made and reflects activities undertaken which were:

- Session development, input to UCL session plan
- Session promotion/audience attraction
- Liaison with interested families
- Arrangements with invited families
- Preparations for session
- Attendance on the day
- Follow up with families post event
- Follow up with UCL post event

Time taken by Societi: 12 days

### Participation in the TSC

Two lay members, representing the PPI perspective supported the TSC. Involvement included (not exhaustively) reviewing and developing patient-facing materials and providing input into protocol design. Suggestions made have been incorporated / addressed. An estimate of time taken can only be made and reflects activities undertaken which were:

- Representative input into the TSC supported by Societi
- Preparation and guidance
- Report preparation/collation

- Papers review
- Attendance and comment
- Feedback and ongoing input as needed

Time taken by our representatives and Societi: 42 days

### Patient advisory initial inputs

Group work – in person and virtually, informed every aspect of our PPI delivery, from detailed technical information based of feedback from families or support resources available within the trial which have been co-crafted by families themselves. This also involved the review of, and development activity for, patient-facing documents and materials. Creating and sustaining our network of families, who have given valued guidance and input involved:

- Topic identification and data collation
- Engagement activities per initiative
- Topic/materials development/ review
- Input co-ordination and aggregation
- Feedback/ongoing input as needed

Time taken by Societi: 124 days

### Development of brochures/educational materials

These materials were developed by the Societi team in collaboration with our families and this has been an iterative process throughout the trial period. As these works were wide ranging in scale, numerous, diverse and have not been logged individually, an estimate of time taken can only be made and reflects activities undertaken which were:

- Course materials content development, production, publication and review
- Family resource development and promotion, publication and review
- KD-CAAP clinician resource folder planning, development and review
- Feedback collation and ongoing development

Time taken by Societi: 248 days



**Thank you**

Thank you for reading our paper. I hope I have been able to convey the broad range of our PPI work, in support of the KD-CAAP clinical trial.

This is by no means an exhaustive overview of what's been achieved – there are many other areas which have both directly and indirectly supported trial awareness, recruitment and clinician knowledge – and many more ways in which our community has been involved in shaping and guiding both the clinical trial and our own work in support of it.

I hope too that I have been able to give you a sense of just how significant KD-CAAP has been to our community – it has brought hope to thousands of families affected by Kawasaki Disease and to all those across our community who remain committed to finding better treatments for children affected by Kawasaki Disease.

Please let me know if there is anything additionally that I can help with, I'd be delighted to discuss any aspect of our work further with you.

With very best wishes,

*Rachael McCormack*

Rachael McCormack, Founder  
Societi, the UK Foundation for Kawasaki Disease



If a child has a **PERSISTENT FEVER**  
and two or more of these symptoms  
**THINK KAWASAKI DISEASE!**



Persistent fever



Cracked lips/  
'strawberry'  
tongue



Rash



Swollen fingers/  
toes



Bloodshot eyes



Swollen glands

# societí

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