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# Welcome to Research matters

**W**e've made huge progress in our understanding of MS over the last 20 years. We now have over a dozen licensed treatments for people with relapsing MS, and some emerging treatments for early active progressive MS.

And excitingly, we now know what's needed to stop MS. But we know that people with MS can't wait.

In October this year, we launched our Stop MS Appeal. We're aiming to raise £100 million to speed up MS research and find treatments for everyone with MS. You can read more about the Stop MS Appeal on **page 24** of MS Matters.

In this issue of *Research matters*, we take a look at the research process and some of the hot topics in MS research at the moment.

Turn to **page 4** to find out more about the journey a drug takes from an idea in the lab to a licensed treatment. And on **page 18** you can read about how we hope to speed up clinical trials – and how you can help.

On **page 6**, Dr Carl Tucker explains how a tiny tropical fish is helping us find new treatments for MS. And hear the latest in heat sensitivity research from scientists at Queen Mary University of London on **page 12**.

As always, we'd love to hear what you think about *Research matters* and if you'd like to be involved. You'll find contact details on the left hand side of this page.



Photo: Jon Bradley

**Dr Susan Kohlhaas**

Director of Research

**contribute**

Our Research Network are a group of people affected by MS who help to shape our research programme. To find out how you can get involved, visit [mssociety.org.uk/researchnetwork](http://mssociety.org.uk/researchnetwork)

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If you'd like to talk to someone in confidence about any of the topics raised in the magazine, our MS Helpline is here for you. Call for free on **0808 800 8000**, or email **helpline@mssociety.org.uk**

**Research matters** is available as an audio download. For details, phone **0300 500 8084** or visit **mssociety.org.uk/Research-Matters**

# The journey of a drug

It takes a long time to develop a new treatment for MS. In 2019, ocrelizumab (Ocrevus) became the first drug to be available on the NHS for people with primary progressive MS. We take a look at the years of progress that led up to this point



## Clinical trials

If a treatment looks promising in the lab, it can move into clinical trials to test the safety and benefits in people.



## The bright idea

All research starts with an idea. It's hard to pinpoint one single moment that sparked the journey of ocrelizumab. But a key event was the publication of results from a clinical

trial of a different drug. These results pointed to a type of cell called a B cell as important in MS.

Armed with this knowledge, scientists headed back to the lab to test their theory.

1

2

3



## In the lab

There are a lot of tools that scientists use in the lab. Researchers around the world used different methods to find out more about the role of B cells in MS and how to use that knowledge to develop a new treatment.

## Cells in a dish

One way to better understand how cells function is to put them in a dish and examine them up close using a microscope.

## Human tissue

Although animals provide valuable information, MS is a uniquely human condition. So to fully understand what's going on we also need to use human tissue.

Brain and spinal cord tissue from the MS Society Tissue Bank was used to better understand the role of B cells in MS. To find out more about the Tissue Bank, visit [mssociety.org.uk/tissue-bank](http://mssociety.org.uk/tissue-bank)

## Animal research

Researchers looked at how B cells behaved in mice with an MS-like condition.

It is a legal requirement in the UK for all drugs to be tested in animals before they are tested

in humans. You can read more about research using animals on [page 6](#).



**Phase 1**

The first phase of clinical trials tests the treatment in a small group of people to check that it's safe, measure the side effects and decide how it should be given.

Ocrelizumab was similar to a drug that had already been through early testing. So scientists already knew it was generally safe for people without MS and could skip phase 1 trials.

**Phase 2**

If a treatment is safe and the side effects are tolerable, it goes into a Phase 2 trial to test the benefits for people with MS.

The results of a phase 2 trial comparing ocrelizumab to a placebo in 220 people with relapsing MS were positive. Very few serious side effects were seen. So the drug moved to phase 3 trials.

**Phase 3**

Phase 3 trials compare the new treatment with the current standard treatment.

Ocrelizumab was tested for people with relapsing MS in two phase 3 trials named OPERA 1 and 2. By running more than one trial, we can be sure we fully understand the effects of the treatment. The company manufacturing the drug also ran a phase 3 trial for people with progressive MS called ORATORIO.

The results of these trials showed that ocrelizumab could reduce relapse rates and slow progression.

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**Making treatments available****Licensing**

A treatment shown to be safe and effective is submitted for a licence. In 2017, ocrelizumab was licensed by the European Medicines Agency (EMA) for people with relapsing MS and early primary progressive MS.

A licensed treatment can be privately prescribed in the UK. But there is a final step for it to be available on the NHS.

**Getting a treatment on the NHS**

For a treatment to be routinely available on the NHS it needs to be reviewed by the National Institute for Health and Care Excellence (NICE), and the Scottish Medicines Consortium (SMC) for patients in Scotland. Authorities in Northern Ireland and Wales usually follow NICE recommendations. They look mainly at cost effectiveness.

In 2018, ocrelizumab was approved by NICE and the SMC as a treatment for relapsing MS. It was initially rejected by NICE as a treatment for early primary progressive MS, but was made available in May 2019 after the drug company dropped its price. We are still waiting for a decision from the SMC.

**Speeding up clinical trials**

Going from a scientific idea to a new treatment can take around 15 years. We want to reduce the time it takes to develop new treatments for people living with MS. You can read more about how we plan to do this on **page 18**.

**Long term safety monitoring**

Treatments are monitored for years even after they are licensed, to make sure we are keeping track of any side effects.

Sometimes further trials are also conducted to test specific aspects of the drug. A new trial of ocrelizumab called ORATORIO-HAND is currently being planned. This will look at the effect of ocrelizumab on hand function in people with MS who use wheelchairs.



# Zebrafish are making a splash

Zebrafish, named for their black and white stripes, are helping us answer some big questions about MS. **Dr Carl Tucker**, Aquatics Facilities Manager at the University of Edinburgh, tells us about the work he does to look after these tiny fish.



laboratory, but we really need to know how all these cells interact with each other. And for that you need a living organism.

I work closely with Professor David Lyons, a researcher based here at the University of Edinburgh. He's doing some brilliant research on zebrafish and MS. And our zebrafish are also used to study all sorts of other conditions, like heart disease, various cancers and kidney function, to name a few.

## Good science needs good animal welfare

We take the welfare of our fish very seriously. In fact, at Edinburgh there's an entire department dedicated to the care of research animals. The UK's laws around animal research are among the

**A**fter nine years serving in the British Army, I returned to the UK to do a marine biology degree, followed by a PhD. I went on to set up the first zebrafish facility at the University of Edinburgh. We now have over 3500 fish tanks, which are home to tens of thousands of zebrafish.



Unlike humans, they can regenerate all their organs - even the heart! But for scientists, the best thing about zebrafish is that the embryos are almost completely transparent. So you see all the processes going on inside their bodies.

## Sharing our DNA with fish

It might seem surprising that fish can help us understand human conditions like MS, but we actually share approximately 70% of our DNA with zebrafish. We can find out a lot of important information just from looking at individual cells in a

## A special little fish

Zebrafish are pretty unique. At five days old, a zebrafish embryo is only 5mm long but is practically a complete fish with all its major organs.

most stringent in the world. Scientists who use animals in their research do a lot of training and are required to get lots of different licenses. The government can do inspections and if a lab is found to be violating the law, it can have very serious consequences and the research can be stopped.

Our zebrafish are fed three times a day with a special balanced diet, and the water quality is constantly monitored to make sure it's ideal at all times.

Under UK law all experimental procedures must assess the possible harms to an animal. The

vast majority of procedures are considered mild – this means the impact on the fish is minimal. If it's possible that pain may occur, we let the fish swim about in a bath of a liquid containing anaesthetic, which they take in through their gills.

I know some people find it peculiar that fish are used for medical research, but if we want to stop conditions like MS, we need animals to help us understand them. I love my job, because we're working to help people living with painful and debilitating conditions.

## The MS Society's position on the use of animals in research

Funding research that uses animals is not a decision we have taken lightly. Research using animals is vital in advancing our understanding of MS. And it's been critical in the development of new treatments. Many current disease modifying therapies were only possible as a direct result of testing and experiments involving animals.

We're actively supporting innovative alternatives that can reduce the number of animals used in research. For example, our researchers are now growing human stem cells in a dish for basic experiments. And the MS Society Tissue Bank helps researchers all around the world use donated post-mortem tissue when this is a suitable alternative.

All our research is reviewed by an independent ethical board, usually at a hospital or university. This is made up of both scientists and members of the public. Before any project can go ahead, the board must be persuaded that there is no suitable alternative to the use of animals.

We expect all our researchers to follow the principle of the 3Rs of animal research and:

- Reduce the number of animals used
- Refine experiments to minimise any suffering
- Replace animal experiments with alternatives wherever possible.

We are signatories to the Concordat on Openness which commits scientists to be open and honest about the ways in which animals are used in medical research.



## Zebrafish and MS

Professor David Lyons and his team are doing lots of different projects with zebrafish to better understand MS.



### Clearing up myelin debris

This project is looking at how myelin debris is cleared in the brains of zebrafish. By testing the effect of different drugs on the rate of clean-up, David and his team aim to identify potential myelin repair treatments for MS.

### Can you have too much myelin?

David has also looked at what happens in zebrafish and mice when myelin-making cells make more myelin than the nerve fibres need. He found that when excess myelin was present, it was sent to the wrong part of the nerve.

### Using robots to study myelin repair

Researchers have developed a new way to study myelin repair in zebrafish, using a machine with a robotic arm. The fish travel along a tube and are put under a high-powered microscope which can count their myelin-making cells in seconds.

# Talking transition

**Becky Perry** lives with MS and is a member of our Research Network. She spoke with **Dr Don Mahad**, a consultant neurologist based at the University of Edinburgh, to find out what we know about the transition from relapsing to progressive MS

## Predicting progression

When I was diagnosed with MS 20 years ago, the neurologist told me that everyone with relapsing MS will at some point transition to secondary progressive MS. This was a common belief at that time, and prompted my first question for Don – does everyone transition from relapsing to



DR DON MAHAD



BECKY PERRY

secondary progressive MS?

As someone with a diagnosis of relapsing MS, I was relieved to hear that the answer is no. “Like everything with MS, the transition from relapsing MS to secondary progressive MS is different for everyone” says Don. “But we know that not everyone with relapsing MS goes on to be diagnosed with secondary progressive MS. One thing that the research has shown is that early treatment with a disease modifying therapy (DMT) can delay transition.”

## Tools to identify transition

There is still a lot of uncertainty surrounding the transition from relapsing to progressive MS. “We don’t currently have any tests to predict who might transition” says Don. “I’d like to see more research into tools to help identify changes that indicate transition.”

He’s part of a team working to develop a gait analysis tool to do just this. “The new system will track how someone’s walking changes over time, giving us a better way to determine when progression has started” says Don. “So far we’ve tested it in people with stable relapsing MS. We observe their gait before and after 20 minutes of exercise.” Around half of individuals had noticeable changes after exercising.

If these exercise-related changes get more obvious over time, it’s a potential sign that someone’s MS may be progressing. “Tracking someone’s results with this tool could help neurologists identify when a person’s MS might be progressing.”



### Better conversations

While a tool for tracking MS progression would be hugely helpful, Don also stressed that there also needs to be a greater dialogue between the neurologist and person living with MS about any changes to their MS – however small.

“I have patients who I only see once a year who seem to be doing well and tell me that everything is fine. But in reality this often isn't accurate, because they have begun to notice small changes – like struggling with hand strength, scuffing their feet and taking longer to do things. They might also be having psychological challenges. Things like these can be real predictors of progression, but when they aren't mentioned the neurologist isn't alerted.”

### Changing the way we view transition

To help these conversations happen, Don thinks we need to change the way we view transition.

“Currently, a diagnosis of secondary progressive MS can affect someone's eligibility for certain treatments. So neurologists often delay changing someone's diagnosis to secondary progressive MS” says Don.

Transition is currently seen by many people as a short period that happens right before you get

secondary progressive MS – however this often isn't the case. Don believes that we need to start viewing transition as a continuous process, rather than a distinct stage of MS.

“The transition from relapsing to progressive MS is gradual” Don stressed. “There might be progressive-like symptoms that don't necessarily lead to secondary progressive MS. Being more open about transition and getting a clear picture of what's going on will help us to give our patients the best outcomes.”

**“There needs to be greater dialogue between the neurologist and person living with MS about any changes to their MS – however small”**



# Your questions answered

We answer your questions on hormones, pregnancy and clinical trials

## Q Do hormones affect MS?

We think sex hormones like oestrogen and testosterone may play a role in MS. Women of reproductive age are almost three times more likely to be diagnosed with MS than men. And although men are less likely to be diagnosed with MS, the course of the condition is often more severe in men.

It's likely that hormones affect activity in our immune systems or how our nerve cells stay safe and healthy. Researchers are trying to find out more about the role different hormones play in MS. We hope understanding how hormones are linked to MS could lead to new targets for treatments.

But hormones are only part of the story, and don't fully explain the differences in MS between men and women.

Researchers think genetic and environmental differences are also a key part of the puzzle.

## Q Should I take part in clinical trials?

Clinical trials test whether new treatments are safe and effective. A huge range of potential treatments are now being tested in MS.

Each trial will have different eligibility criteria, which determines who can take part. You can find out about the different clinical trials currently recruiting people with MS using the NHS Be Part of Research website: <https://bepartofresearch.nihr.ac.uk/>

There are many advantages of taking part in clinical trials. You may gain access to treatments that aren't yet available on the NHS. You'll need regular tests and appointments, so you could benefit from more

frequent contact with a medical professional. And you'll be playing an active role in your own healthcare and helping others by contributing to medical research.

But taking part in a clinical trial is a big decision, and it's important to weigh up the potential benefits and risks. The treatment being tested might potentially have harmful side effects, or no effect at all. And being in a trial can take a great deal of commitment and time.

If you have any questions about being in a clinical trial you can speak to your doctor, MS nurse or neurologist.

## Q Should I become pregnant if I have MS?

Having MS shouldn't stop you having a baby. Recent research has shown that pregnancy does not have any long-term harmful effects on MS. And although children





Photos: iStock

### Getting the right advice

Our research staff are not medical professionals. This page is designed to provide general information. If you have specific health questions, please talk to your health care professional.

who have a parent with MS have a higher risk of developing the condition than the general population, the risk is still very small at 1.5%.

Women with MS often experience fewer relapses during pregnancy,

particularly during the third trimester. But in the three months after giving birth, around a third of women experience relapses at a higher rate than before they became pregnant. However, recent research suggests if you compare the entire year before pregnancy with the entire year after the birth, there's no overall difference in relapses.

Because we know that it's important for people with MS to start treatment as soon as possible after their diagnosis, new UK guidelines recommend women with MS should

not delay starting treatment, even if they want to become pregnant in the future. They also recommend women who become pregnant don't immediately stop taking their medication without a discussion with their neurologist or nurse.



If you'd like to talk in confidence about any aspect of living with MS, you can call our Helpline free on **0808 800 8000**, or email **helpline@mssociety.org.uk**

**H**eat sensitivity is a common side effect of MS, and has long been associated with the condition. “Before we had MRIs, diagnosing MS involved ‘the hot bath test,’” says Dr Mark Baker, a researcher at Queen Mary University of London. “Patients were placed in a hot bath to see if symptoms worsened when they got warm.” Although it is not actually a symptom itself, many people find that a rise in their body temperature can make their existing MS symptoms worse.



SARAH REES



DR MARK BAKER

LAVINIA  
AUSTERSCHMIDT

“It’s a small thing in some ways, but it can also be terrible,” says Lavinia, a PhD student also working at Queen Mary. “For some, just getting excited raises their temperature enough to cause some debilitating symptoms, and there’s currently no treatment to help.” For many, the best medical advice is to have a cold bath and avoid over-exercising.

But researchers like Lavinia and Mark believe that a better understanding of what’s going on in the brain and spinal cord, including why nerves react to



# Heat sensitivity research is hotting up

Research Network Member **Sarah Rees** quizzed PhD student **Lavinia Austerschmidt** and researcher **Dr Mark Baker** about their work into heat sensitivity in nerve fibres



temperature rises, could help us develop drugs to reduce the symptoms associated with heat.

### Optic nerves under the microscope

Researchers know that myelin damage in MS makes it difficult for messages to be passed along our nerves. And heat makes this worse by making messages shorter and harder to pass on. This leads to the worsening of

symptoms many people with MS experience in the heat.

Mark and his team may have found another reason for heat sensitivity. They have been looking at the nerve responsible for vision – the optic nerve. This is important in MS because the first symptom people often notice is optic neuritis (blurred vision), caused by inflammation in the optic nerve.

They have discovered that optic nerve fibres become less responsive when it's hot, which makes it harder for messages to get through. This is a temperature-dependent change that hadn't been seen before.

### Your tips for dealing with the heat

We may be on our way to Christmas now, but this year we had a record-breaking hot summer. We asked our Twitter followers about their top tips for keeping cool in the heat.

“I find carrying an old school fan really helps. I have a selection of different styles for different outfits!” – Gem

“I keep cooling mist spray in the fridge at home and at work” – Marianne

“I have cold baths, sleep with a wet sheet over me and use my dog's cooling mat” – Nikky

“At night I put ice packs in a pillow and place it under my legs” – Harveel



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Lavinia is now investigating the reasons for this effect.

### What comes next?

This discovery represents an important first step towards developing a drug to target heat sensitivity. “Now that we know what's going wrong, we're also on our way to finding out what we need a drug to target,” says Mark.

“We want to continue to look at nerves in other parts of the brain. We would then need to work with researchers from other areas of science to find potential drugs.”

When developing drugs, it's also important to remain aware of the other problems that people with MS face. “One drug could have an impact is bumetanide. But we also know that it causes increased urination and is very poor at getting into the brain.” As bladder and bowel problems are common in people with MS, there is a risk such a drug could make these symptoms worse.

But continuing research into heat sensitivity could find other treatments which act in a similar way, without the unwanted side effects.

### Something worthwhile

Medical research is a long and slow process, but both Lavinia and Mark take great pleasure in it. “I think we're addicted” says Mark, who has been involved in MS research since 1984.

“I love being in the lab,” agrees Lavinia. “What I really hope is to find ways to help people.” It's a sentiment echoed by her supervisor. “I got into MS research because I wanted to do something worthwhile,” says Mark.

For those of us with MS, it is encouraging to hear. It is researchers' relentless enquiries that brighten our futures and could change the MS game for the generations to come.

# What do we know about vaccines and MS?

Whether they're given as a sugar cube at school or an injection in the arm before a holiday, most of us are pretty familiar with vaccines. Research Network member, **Lyndsey Shellard**, quizzed **Professor Gavin Giovannoni** from Queen Mary University of London to find out what we know about vaccines and MS

## What are vaccines and what are they used for?

"Vaccines teach our immune system how to fight infections, so that our bodies know how to protect us from them later. In the UK, we usually have a series of vaccinations as children. Since

vaccines were invented, many diseases, like smallpox, have been eradicated.

When most of the population is vaccinated against a disease, it creates 'herd immunity'. As most people are protected, the likelihood of the disease spreading is significantly reduced. If lots



LYNDESEY SHELLARD

of people stop having the vaccine, the disease can come back. This is unfortunately what happened with the MMR vaccine during the 1990s. As a consequence, we are now seeing a resurgence of measles, despite the vaccine being safe."



PROF GAVIN GIOVANNONI

## Do vaccines cause MS?

"There is no evidence to suggest that vaccines can cause someone to develop MS. Recent studies have looked at a possible link between MS and the vaccines for influenza, measles, mumps and rubella and human papillomavirus, amongst others.

**“There is no evidence to suggest that vaccines can cause someone to develop MS.”**

They found no association between these vaccines and the risk of developing MS.

Researchers are still investigating whether any vaccines may actually protect you from developing MS.”

### **Are vaccines safe for people with MS?**

“All vaccines undergo strict safety testing. But since they affect the immune system, people with MS do need to be careful about which vaccinations they receive.

There is no evidence that vaccinations can cause relapses or make your MS progress more rapidly. But there are some instances where we wouldn't advise people with MS to receive a vaccine – like during or just after a relapse.

And different types of MS treatments can also affect which vaccines you can receive. For example, if you are taking beta interferons, you can have all types of vaccines, and the drug shouldn't impact how well the vaccine works. But if you're taking a drug that suppresses your immune system, like steroids or ocrelizumab, live vaccines could put you at risk of developing the disease they're meant to protect against. This is because these vaccines contain a weakened form of the infection. If you stop taking drugs that suppress your immune system, your levels of immune cells need to recover before you have a live vaccine.”

### **So should people with MS get vaccinated?**

“Ultimately, it depends on the treatment they are taking. I'd recommend that people with MS talk to their doctor or other healthcare professional to find out which vaccinations they should receive. And the people around them, like family and carers, should make sure they've had all the standard vaccines.”



This page is designed to give general information about vaccines. Always talk to your healthcare professional before making any decisions about your own healthcare.

# Meet the researcher

**Sarah Bittlestone** lives with MS and is a member of our Research Network. She caught up with **Dr Anisha Doshi**, a researcher at University College London, to find out about her journey into MS research

## Hi Anisha! What made you want to work in MS research?

“My father was diagnosed with secondary progressive MS when I was two years old. As I grew older, his MS progressed quickly, but I was always inspired by his belief that something



SARAH BITTLESTONE

would come along to stop MS and by his determination to help that happen. As a child, I was unaware of the true impact of MS on our lives. I have learnt that he took part in every trial he was able to and volunteered at the local MS Society group.

He was a great role model, but his impact on my career wasn't immediately obvious. When I started thinking about what sort of job I wanted to do, I knew that I didn't want to sit behind a desk all day. I'm creative and I love talking to people. I also love

science. This desire to do more of what I'm good at led me to medicine.

As part of my medical degree I spent a year working on a neuroscience research project. My personal connection with MS had given me an interest in myelin damage, so I spent the year investigating myelin damage in rats. I really enjoyed the project, but a stint in clinical research made me realise that I wanted to do research with people affected by MS.”

## What projects are you working on at the moment?

“I've put my neurology training on hold for now so I can do a PhD. We're using functional magnetic resonance imaging (fMRI) to look at how the connections between different areas of the brain communicate with each



DR ANISHA DOSHI



ANISHA'S WORK USES MRI SCANS

other when the brain is at rest, and how this changes in secondary progressive MS and with cognitive problems.

I noticed that many of my patients with MS told me in the clinic that they thought they were cognitively impaired – they could ‘feel’ it – but other than referring them for psychological testing there was little I could do to help. I realised that we understand very little about this important and common symptom, and have no effective treatments. However, there is a growing interest in the effect of conditions like MS on cognition, and I’m excited to see this area of research move forward.

I am also currently working with Professor Jeremy Chataway on the MS-STAT2 trial. We’re looking at whether the cholesterol lowering drug simvastatin can help slow disability progression in people with secondary progressive MS. The first trial was positive, so we’re hoping to confirm this in a larger group.”

The MS-STAT2 trial is still recruiting participants. If you’d like to take part, you can register your interest at:

**[ms-stat2.info](https://www.ms-society.org/MS-STAT2)**

### **What do you find most rewarding about working in research?**

It’s a really exciting time to be involved in research. I can offer my patients and their families real hope for the future, which wasn’t the case when I was growing up. And one of the things I really love about my research is the amount of time I get to spend with patients – much longer than the 15–30 minutes per person allocated in NHS clinics.

It can still be challenging to be a woman in the academic world. And it can be difficult to balance both the

research, clinical and personal aspects of my career. But I know that my experience in research will ultimately give me a deeper understanding of the effects MS has on my patients.”

### **Finally, what recent developments in MS research have been the most exciting for you?**

“The licensing of ocrelizumab for primary progressive MS. This seemed impossible when I graduated 10 years ago, and really is a key landmark to be celebrated!”



