Sarah Cannon Research Institute UK Limited

# Sarah Cannon Research UK

**Inspection report**

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

## Ratings

| | |
|---|---|
| Overall rating for this location | Good |
| Are services safe? | Good |
| Are services effective? | Insufficient evidence to rate |
| Are services caring? | Good |
| Are services responsive to people's needs? | Good |
| Are services well-led? | Good |

# Summary of findings

## Overall summary

We rated this service for the first time. We rated it as good because:

- The service had enough staff to care for patients and keep them safe. Staff had training in key skills, understood how to protect patients from abuse, and managed safety well. The service-controlled infection risk well. Staff assessed risks to patients, acted on them and kept good care records. They managed medicines well. The service managed safety incidents well and learned lessons from them.
- Staff provided good care and treatment, gave patients enough to eat and drink, and gave them pain relief when they needed it. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.
- Staff treated patients with compassion and kindness, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients, families and carers.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for treatment.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service engaged well with patients and the community to plan and manage services and all staff were committed to improving services continually.

However:

- The design and use of facilities of one treatment room made it feel cluttered and cramped when fully occupied by staff, patients and visitors.

# Summary of findings

## Our judgements about each of the main services

| Service | Rating | Summary of each main service |
|---|---|---|
| Medical care (Including older people's care) | Good  | |

# Summary of findings

## Contents

# Summary of this inspection

## Background to Sarah Cannon Research UK

Sarah Cannon Research Institute UK was a dedicated clinical trials unit for cancer patients. Sarah Cannon Research UK was a location provided by Sarah Cannon Research Institute UK Limited, which was part of the wider HCA UK network of providers and locations. The unit offered early phase clinical trials and was supported by the global centres in clinical research. The service was located in Harley Street, London. All care is physician led, with the unit being led by a consultant. The location provided service to cancer patients over 18 years of age from the local community, nationally and some international patients. The unit was open to both NHS and private patients and there was no cost to the patient of participating in a clinical trial.

The service comprises of 2 consulting rooms and three treatment rooms with a total of 12-day case places (two beds and 10 chairs). Treatment room one had two beds for patients staying for approximately 12 hours, treatment room two had four chairs in private pods for patients staying approximately six hours and treatment room three had six chairs in an open environment for patients staying approximately four hours.

The regulated activities the service is registered for is:

- Treatment of disease, disorder or injury

There was a registered manager in place at this location since it registered with the CQC.

The main service provided by this hospital was cancer services.

## How we carried out this inspection

We conducted an unannounced inspection of this location on the 22 November 2022. We conducted staff interviews over video conference call on 1 December 2022. During the inspection we spoke with 13 members of staff which included medical, nursing, managerial and administrative staff. We spoke to five patients and visitors. We looked at ten sets of patient records. The inspection team consisted of a lead inspector and specialist advisor. The inspection was overseen by Nicola Wise Head of Hospital Inspections for London.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

## Outstanding practice

We found the following outstanding practice:

- The service had introduced a safeguarding screening tool in March 2022 because staff had recognised that the service had never raised a safeguarding concern. The provider wide governance and safeguarding teams assisted staff working in the service to create and test the new safeguarding screening tool.
- The service had introduced art therapy boxes to improve the patient experience whilst patients were having their treatment.

# Summary of this inspection

- The service had participated in a world first cancer vaccine trial in November 2021. The service was amongst one of the world's first centres to administer a cancer vaccine as part of a longer-term global trial to see if vaccines may be an effective measure in the prevention of cancer.
- The principal investigators from the service worked as independent academic researchers to review patients' outcomes. We saw an example where the service reviewed the outcomes of colorectal cancer patients enrolled into a phase I clinical trial in the unit during the last 10 years and evaluated the overall response to early phase drugs and survival outcomes. The results are to be displayed in a poster in a prominent international conference in 2023.

## Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

**Action the service SHOULD take to improve:**

- The service should consider changing treatment room three's layout so that it does not feel cluttered and overcrowded when at full capacity.

# Our findings

## Overview of ratings

Our ratings for this location are:

| | Safe | Effective | Caring | Responsive | Well-led | Overall |
|---|---|---|---|---|---|---|
| **Medical care (Including older people's care)** | Good | Insufficient evidence to rate | Good | Good | Good | Good |
| **Overall** | Good | Insufficient evidence to rate | Good | Good | Good | Good |

Good

# Medical care (Including older people's care)

| | |
|---|---|
| Safe | Good |
| Effective | Insufficient evidence to rate |
| Caring | Good |
| Responsive | Good |
| Well-led | Good |

## Is the service safe?

Good

This was the first time we rated safe at this location. We rated it as good.

### Mandatory training

**The service provided mandatory training in key skills to all staff and made sure everyone completed it.**

Staff received and kept up-to-date with their mandatory training. The mandatory training was comprehensive and met the needs of patients and staff. Managers monitored mandatory training and alerted staff when they needed to update their training. At the time of inspection, overall mandatory training compliance for staff was 94%.

### Safeguarding

**Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.**

All clinical staff received training specific for their role on how to recognise and report abuse. At the time of the inspection all clinical staff had completed safeguarding adults level two training and 95% had completed safeguarding children level two training. Safeguarding adults level three training was completed by 89% of eligible staff. Staff could give examples of how to protect patients from harassment and discrimination, including those with protected characteristics under the Equality Act. Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff knew how to make a safeguarding referral and who to inform if they had concerns. The service had introduced a safeguarding screening tool in March 2022 because staff had recognised that the service had never raised a safeguarding concern. The provider wide governance and safeguarding teams assisted staff working in the service to create and test the new safeguarding screening tool. Since the tool's introduction the service has raised and appropriately managed three safeguarding concerns.

### Cleanliness, infection control and hygiene

**The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.**

Clinical areas were clean and had suitable furnishings which were clean and well-maintained. The service generally performed well for cleanliness. The service audited general infection control principles and practices, hand hygiene and

uniform compliance. Data showed that the service scored between 91% and 100% in all audits for the period of October 2022 to May 2022. Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Staff followed infection control principles including the use of personal protective equipment (PPE). Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned. The service held regular infection prevention control committees which had oversight of all infection prevention control issues on a departmental and hospital wide level. Staff followed best practice guidance in cleaning equipment and the environment after patient use. The service had systems in place for the safe management and disposal of clinical waste in line with national guidance.

### Environment and equipment

**The design and use of facilities of one treatment room were not in line with national guidance. The service had enough equipment to keep people safe and staff managed clinical waste well.**

The service had three treatment rooms and two consultation rooms.

Treatment room one consisted of two beds in an individualised space used for patients staying at the service for up to 12 hours.

Treatment room two consisted of four treatment chairs in individualised space for patients staying at the service for up to six hours.

Treatment room three consisted of six chairs in an open plan space for patients staying up to four hours. We found that treatment room three had a layout which had the potential for the room to be crowded when it was at full capacity with staff, patients and visitors accompanying patients. During the inspection we observed that some people including members of the inspection team, patients and visitors had difficulty entering and exiting the room due to the equipment placed in proximity to the door. At the time of the inspection there was a weighing scale placed next to the door, a privacy screen next to the door and a treatment chair which was near the door. Due to the proximity of equipment next to the door it was difficult to enter and exit the room and open the door fully. This meant that the door was at risk of obstruction in case of an emergency. The six treatment chairs alongside their accompanying chairs for visitors were placed close by one another. Nursing staff told us that the room could feel crowded when all the chairs were occupied with patients and visitors. After the inspection the service provided an independent fire risk assessment by an external organisation which showed that the room had minimal fire risk. An external resuscitation risk assessment showed that the room had sufficient space for resuscitation purposes, but the assessment recommended simulation be carried out in order to provide assurance.

The service had placed wheeled privacy screens next to each chair. These screens allowed for limited visual privacy against other seated people, but they were not effective if other people were standing up or moving around the room. We saw evidence to show the service was considering extensive renovations to improve the space and address privacy issues by building individual pods, at the same time the service was also considering changing premises. Managers we spoke with told us that due to the complexity of the issue they wanted to consider all appropriate options and showed us evidence that a decision was likely to be made by the first financial quarter in 2023.

Patients could reach call bells and staff responded quickly when called. Staff carried out daily safety checks of specialist equipment. The service had enough suitable equipment to help them to safely care for patients. Staff disposed of clinical waste safely. The service followed the HCA UK provider wide cytotoxic spillage policy and also had a localised standard operating procedure for staff to follow.

Good

# Medical care (Including older people's care)

### Assessing and responding to patient risk

**Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.**

All patients underwent a thorough assessment prior to being provided treatment on the clinical trial. There was a defined set of information to be provided to the sponsor for the sponsor to check the patient's eligibility for the trial. The on-site resident medical officers (RMO) and clinical research fellows would review any patients of concern. The service had two on-site consultant level doctors who were also able to review patients of concern. Nursing staff reviewed patients at regular intervals as dictated by their clinical trial protocol set by the sponsor. Staff used a nationally recognised tool to identify deteriorating patients and escalated them appropriately as per HCA UK provider wide policy. The service had its own resuscitation team and staff received life support training appropriate to their role. The service would aim to stabilise any deteriorating patient and transfer them to the nearest NHS hospital through "999" services. The service had a pathway in place for suspected sepsis. Patients suspected of neutropenic sepsis were assessed by using a neutropenic sepsis assessment checklist and staff were able to clearly outline the steps taken in the event of suspected sepsis.

Patients were provided with contact details of the research nurse team and they were able to call the service for advice out of hours. Where treatment was not covered by the sponsor due to issues related to disease rather than the clinical trial then the service would liaise with the patient's NHS team to arrange care and treatment.

### Nurse & pharmacy staffing

**The service had enough nursing and support staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave bank and agency staff a full induction.**

The service had enough nursing and support staff to keep patients safe. The service had seven whole time equivalent staff which included a lead nurse, junior sisters, staff nurses, healthcare assistant and ward clerk. Managers calculated and reviewed the number and grade of nurses, nursing assistants and healthcare assistants needed for the safe operation of the clinical trial unit in line with national guidance. The service had no vacancies. The service had a turnover rate of 57%. This was due to four people out of seven leaving in the previous 12 months to this inspection. We saw evidence to show that these staff left mainly for career purposes. The service had a sickness rate of 5%. The service did not utilise any agency nurses in the previous 12 months to this inspection. The service had regular bank staff who would usually work 1 shift on a weekly basis. The ratio of substantive to bank staff was 76% substantive to 24% bank. Managers made sure all bank and agency staff had a full induction and understood the service.

The service had six whole time equivalent pharmacy staff which included a pharmacy manager, lead clinical trial pharmacist, clinical trial pharmacist, clinical trial pharmacist technicians. The service had no vacancies. The service had a turnover rate of 17%. This was due to one person leaving in the previous 12 months to this inspection. We saw evidence to show that this staff member left mainly for career purposes. Sickness rates for pharmacy staff was 3.5%. The service did not utilise any agency staff in the previous 12 months to this inspection. The service had regular bank staff who worked on a full-time basis in the previous 12 months to this inspection. The ratio of substantive to bank staff was 86% substantive to 14% bank. Managers made sure all bank and agency staff had a full induction and understood the service.

### Medical staffing

**The service had enough medical staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave locum staff a full induction.**

Good

# Medical care (Including older people's care)

The service had enough medical staff to keep patients safe. The service had a medical team made up of substantive team members employed directly by the service. The team consisted of principal investigators which were consultant level doctors, sub investigators which were also consultant level doctors but who were not directly employed by the service, clinical research fellow and a bank resident medical officer. The service had a 29% vacancy rate which represented one post in the team. The service had a 50% turnover rate for medical staff which represented two staff members leaving in the previous 12 months to this inspection. We saw evidence to show that these staff left mainly for career purposes. Sickness rates for medical staff were 0.4%. The service did not utilise any agency medical staff in the in the previous 12 months to this inspection. The service had regular bank staff who would usually work to cover sickness or absence. The ratio of substantive to bank staff was 90% substantive to 10% bank. Managers made sure all bank staff had a full induction, had speciality training appropriate to their role in a clinical trial setting and understood the service. The service always had a consultant available during operational hours.

## Records

**Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.**

Patient notes were mostly paper records with some limited electronic records and all staff could access them easily. Records were stored securely in a locked room. The patient notes were individually designed for each clinical trial in collaboration with the pharmaceutical sponsor. The notes were made available to external auditors sent by the sponsor. The external auditors were allowed to see the notes in a secure room with the supervision of a member of staff. Previous treatment notes were available for staff to see through the HCA UK provider wide electronic record system.

## Medicines

**The service used systems and processes to safely prescribe, administer, record and store medicines.**

Staff followed systems and processes to prescribe and administer medicines safely. Patients were thoroughly checked against the sponsor's eligibility criteria before being accepted on to a clinical trial. Clinical trials conducted at the service were either of new drugs or existing drugs being used in a new capacity such as dose changes. Patients were provided with extensive written information regarding the drug and the clinical trial they were being enrolled in. Staff reviewed each patient's medicines regularly in line with clinical trial protocols and provided advice to patients and carers about their medicines. Staff were able to give patients medicine which was stored on-site for the purposes of controlling side effects from the clinical trial drugs. Staff completed medicines records accurately and kept them up-to-date. Staff stored and managed all medicines and prescribing documents safely.

Clinical trial drugs were prepared on-site in line with instructions set buy the trial sponsor. We saw evidence to show that drugs were stored in line with sponsor guidelines and drugs kept in temperature-controlled fridges were monitored on a regular basis. Clinical trial drugs were administered as per the sponsor instructions which could either be intravenously or orally.

Clinical research is conducted according to a plan, known as a protocol, as set out by the trial sponsor. It describes what can and cannot be done as part of a trial and must be adhered to so that trial patient safety, research integrity and local governance can be maintained. A protocol deviation can be described as any deviation from the approved protocol. The service had a protocol deviation standard operating procedure which defined what each type of deviation was and how the service managed such events. There were three types of deviation: minor, major and urgent safety measure. Minor deviations were documented in the patient notes and where appropriate an incident raised using the electronic incident management system. Minor deviations were also documented by the clinical research associate who represented the sponsor following an on-site visit. Corrective action and preventative action plans were completed for any major

deviation. A major deviation was when the deviation from the approved protocol may have affected the safety of the trial patient or the study outcomes. In certain cases, it may be necessary for the sponsor to take appropriate urgent safety measures in order to protect the patients on a trial against any immediate hazard to their health or safety. The service has never identified an urgent safety measure but did receive notifications from sponsors regarding urgent safety measures.

The service has eight permanent members of staff who administered systemic anticancer treatments (SACTs) out of which seven had been assessed to be competent in line with the provider's policy in the 12 months prior to this inspection. One member of staff was enrolled in a UK Oncology Nursing Society (UKONS) course in order to be able to administer SACTs. The service also had four bank members of staff who regularly administered SACT, all of whom had been assessed to be competent within the 12 months prior to this inspection.

### Incidents

**The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team.**

All staff knew what incidents to report and how to report them. Staff raised concerns and reported incidents and near misses in line with provider policy. The service had no never events. A total of 230 incidents were reported in the period of November 2021 to November 2022 out of which 11 were low harm and 219 were no harm. The service had identified six major deviations from clinical trial protocol since January 2022 and reported them to the trial sponsor. Staff understood the duty of candour. They were open and transparent and gave patients and families a full explanation if and when things went wrong. Staff received feedback from investigation of incidents, both internal and external to the service. Staff met to discuss the feedback and look at improvements to patient care.

## Is the service effective?

Insufficient evidence to rate

There was insufficient evidence for us to rate effective at this service

### Evidence-based care and treatment

**There was insufficient evidence for us to rate this service because the service provided care and treatment for patients on early phase trials based on guidance for clinical trials and research. Managers checked to make sure staff followed guidance.**

Staff followed up-to-date policies to plan and deliver clinical trials according to industry guidance and the pharmaceutical sponsor requirements. The service regularly monitored working practices against the pharmaceutical sponsor requirements and implemented corrective action where deviations in working practices occurred. All clinical trial protocols were approved by the medicines and healthcare product regulatory agency (MHRA) and the HCA Research Review Committee. Regular meetings were held with the pharmaceutical sponsor companies in relation to reviewing and updating clinical trial protocols. The protocols management team ensured all treatments were in line with the HCA UK provider wide protocol management framework.

### Nutrition and hydration

**Staff gave patients enough food and drink to meet their needs and improve their health. The service made adjustments for patients' religious, cultural and other needs.**

Good

# Medical care (Including older people's care)

Staff made sure patients had enough to eat and drink, including those with specialist nutrition and hydration needs. Staff checked with patients every day how they were coping with eating at home and they monitored patient's fluid and nutrition intake where needed. Patients had access to on-demand dining with a selection of food options catered towards all dietary needs.

### Pain relief

**Staff assessed and monitored patients regularly to see if they were in pain, and gave pain relief in a timely way. They supported those unable to communicate using suitable assessment tools and gave additional pain relief to ease pain**.

Staff assessed patients' pain using a recognised tool which had prompts for staff to help them assess pain for patients with communication difficulties and gave pain relief in line with individual needs and best practice. Patients received pain relief soon after requesting it. Staff prescribed, administered and recorded pain relief accurately.

### Patient outcomes

**There was insufficient evidence for us to rate this service because outcome data that was collected was for early phase clinical trials. Managers monitored compliance against provider policy and clinical trial requirements. They used the findings to improve the service. The service had been accredited under relevant clinical accreditation schemes.**

The service was a phase one clinical trial unit which meant that it was part of a wider network of centres working with pharmaceutical sponsor companies in the testing and development of new or existing cancer drugs. The sponsor companies would collect data from the service alongside data from other centres and analyse it to determine the outcome of the clinical trial. When a clinical trial was completed the outcomes of the trial were published in peer-reviewed journals. The principal investigators employed by the service would be expected to contribute to the writing and review of these papers. Staff explained that the service is associated with over 60 publications since it opened in May 2013. The Managers and staff carried out a comprehensive programme of repeated audits to check compliance against provider policy and sponsor company requirements. The service had a monthly audit review meeting where team members reviewed all departmental and observational audit results, along with trial sponsor audit schedules, corrective action and preventative action plans and findings. Managers used information from the audits to improve compliance with clinical trial protocols and provider policy. The service was accredited by The European Society for Medical Oncology as part of a provider wide accreditation. The accreditation designated the provider as a centre that provides highly integrated oncology and palliative care services. The service was also accredited for ISO 9001:2015 quality management system by BSI.

### Competent staff

**The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.**

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. Medical staff that were appointed as principal investigators had to have completed specialist training, had significant experience as a sub-investigator and have a proven track records of continuous professional development (CPD) activities in the form of high standard national and international educational event participation and be active in publications in peer reviewed journals. Principal investigators were required to complete specialist mandatory training conducted by the sponsor company regarding each clinical trial protocol before overseeing a new trial protocol. We saw evidence to show that nursing staff and pharmacy staff participated in CPD events such as national and international conferences. The service held monthly lunch time CPD learning events.

Good

# Medical care (Including older people's care)

Managers gave all new staff a full induction tailored to their role before they started work. Managers made sure staff received any specialist training for their role. Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. Managers supported staff to develop through yearly, constructive appraisals of their work. Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. Managers identified poor staff performance promptly and supported staff to improve. Managers made sure staff attended team meetings or had access to full notes when they could not attend.

### Multidisciplinary working

**Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.**

Medical staff attended regular and effective multidisciplinary meetings to discuss patients and improve their care. Principal investigators and sub-investigators attended various HCA UK provider wide multidisciplinary meetings to present the trials the service was conducting for a particular tumour type. Staff worked across health care disciplines and with other agencies when required to care for patients. Staff from the service liaised directly with the patient's NHS hospital team, GP and where required their palliative care team to co-ordinate the patient's care and treatment. Staff referred patients for mental health assessments when they showed signs of mental ill health.

### Seven-day services

**Key services were available seven days a week to support timely patient care.**

The service was available Monday to Friday between 8.30am to 6.00pm, on-call support was available for patients out of hours and on weekends. Staff could call for support from doctors and other disciplines, including mental health services from both HCA UK locations and the patient home NHS team.

### Health promotion

**Staff gave patients practical support and advice to lead healthier lives.**

The service had relevant information promoting healthy lifestyles and support in clinical areas. Staff assessed each patient's health when admitted and provided support for any individual needs to live a healthier lifestyle.

### Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

**Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.**

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Staff gained consent from patients for their care and treatment in line with legislation and guidance. Staff made sure patients consented to treatment based on all the information available. Staff clearly recorded consent in the patients' records.

## Is the service caring?

Good

This was the first time we rated caring. We rated it as good.

Good

# Medical care (Including older people's care)

### Compassionate care

**Staff treated patients with compassion and kindness and took account of their individual needs. However, some patient's privacy was affected due to the size of a treatment room.**

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. Patients were provided with their care or treatment in individual bays where curtains could be closed in treatment rooms one and two. However, in treatment room three patients had limited privacy due to the amount of space. This was represented in the patient feedback survey as metrics used to measure patient satisfaction in relation to privacy scored between 60% and 100% for the period of May 2022 to October 2022. Patients said staff treated them well and with kindness. Staff followed policy to keep patient care and treatment confidential. Staff ensured that treatment records were kept anonymous to the external auditors that came to review the clinical trial on a regular basis. Staff understood and respected the personal, cultural, social and religious needs of patients and how they may relate to care needs. For the period of May 2022 to October 2022 between 85% and 100% of patients would recommend the service.

### Emotional support

**Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.**

Staff gave patients and those close to them help, emotional support and advice when they needed it. Staff conducted a holistic needs assessment using a developed tool. Staff at the service were able to access a range of support services from the wider HCA UK provider network. All patients were able to be referred to the Macmillan cancer information centre located in another HCA UK hospital nearby. Patients had access to art boxes which were introduced to improve the patient experience. Staff explained that patients found it therapeutic to do art whilst having their treatment. Staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations. Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them.

### Understanding and involvement of patients and those close to them

**Staff supported patients, families and carers to understand their condition and make decisions about their care and treatment.**

Staff made sure patients and those close to them understood their care and treatment. Staff talked with patients, families and carers in a way they could understand, using communication aids where necessary. Patients and their families could give feedback on the service and their treatment and staff supported them to do this. Staff supported patients to make advanced decisions about their care. Staff supported patients to make informed decisions about their care. Patients gave positive feedback about the service.

## Is the service responsive?

Good

We rated responsiveness for the first time. We rated it as good.

Good

# Medical care (Including older people's care)

## Service planning and delivery to meet the needs of the local people

**The service planned and provided care in a way that met the needs of patients using the service. It also worked with others in the wider system and local organisations to plan care.**

Managers planned and organised services, so they met the changing needs of the patients using the service. The service was able to refer patients to Macmillan support centres hosted at other locations run by the wider HCA UK network. The service had systems to liaise with patients NHS teams in case the patients needed additional support or specialist intervention. Managers monitored and took action to minimise missed appointments. Before patients were started on a trial staff went through their schedule with them and rearranged any appointments they may have in order to accommodate the patient's treatment session whilst on the trial. This was done to prevent non-attendance as this could result in the patient being removed from the clinical trial. In the period of November 2021 to October 2022 there have been 3367 patient attendances and one non-attendance. Managers ensured that patients who did not attend appointments were contacted.

## Meeting people's individual needs

**The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.**

Each clinical trial had its own eligibility criteria set by the sponsor company which outlined which type of patient was suitable for the trial. Patients were only able to be admitted to a clinical trial if they were eligible according to the specific criteria, the principal investigator and clinical research nurse assessed patients holistically to see if they could meet the requirements of the trial. Most clinical trials held at the service stipulated that a patient must have the capacity to provide written informed consent, as such most patients living with mental health problems, learning disabilities and dementia were uncommon in participating in the trials. This was because sponsor companies reasoned that patients with significant comorbidities or with psychological, familial, sociological or geographical conditions could compromise the patient's safety, or ability to adhere to the protocol or compromise the integrity of the study outcome. Judgement regarding these criteria was usually left to the principal investigator. We saw examples of when the service accommodated patients with physical disabilities such as blindness to be entered into a clinical trial.

At the start of a patients journey an individual needs assessment was carried out which outlined any measures the service needed to take to facilitate the patient's participation in the trial. Patients were given an allowance for accommodation, travel and food expenses by the sponsor company. Patients were able to claim back any expenses or allow the service to book and manage accommodation and travel. There was a hotline number for out of hours contact if there were any issues for the patient.

The service had information leaflets available in languages spoken by the patients. Managers made sure staff, and patients, loved ones and carers could get help from interpreters or signers when needed. Patients were given a choice of food and drink to meet their cultural and religious preferences. The service could accommodate patients requiring prayer, meditation or contemplation space by providing a quiet consultation room.

## Access and flow

**The service aimed to provide access to clinical trials for patients meeting the eligibility criteria. Staff worked to reduce waiting time from referral to trial consent.**

Good

# Medical care (Including older people's care)

Clinical trial opportunities for patients were mostly based on competitive recruitment. This meant staff at the service had to complete a prompt review of potential trial candidates as high priority and the service clinicians maintained direct communications with referring consultants by email to provide preliminary feedback on potential options available to the patient.

The service had a patient management standard operating procedure which described the patient recruitment process in detail. All referrals were tracked on the service patient referral tracker and progress was monitored by managerial staff. Recruitment coordinators collected all relevant information from the referring team. The principal investigators reviewed patient referral letters and relevant documentation and completed documentation indicating whether a clinical trial option was for the patient. The service aimed to complete the patient initial eligibility review within 2 working days. After the service received all the patient's relevant documentation from the referrer a written confirmation was sent to the referrer to inform them of the outcome. If a trial option was available and the patient was eligible, then the patient was contacted by the referring team and invited to the service to discuss logistics and the rational of the trial. Some trials had additional testing or checks in place to determine eligibility, this affected the review time, but the average time between receiving the referral and trial consent appointment was 17 days for the 12 months prior to this inspection.

### Learning from complaints and concerns

**It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.**

Patients, relatives and carers knew how to complain or raise concerns. The service clearly displayed information about how to raise a concern in patient areas. Staff understood the policy on complaints and knew how to handle them. Managers investigated complaints and identified themes. Staff knew how to acknowledge complaints and patients received feedback from managers after the investigation into their complaint. The service was able to escalate complaints to the Independent Healthcare Sector Complaints Adjudication Service (ISCAS) if a patient was dissatisfied with the service's response to a complaint. The service followed the ISCAS code of complaint management. There were no formal and one informal complaint in the previous 12 months prior to this inspection. No complaints were escalated to ISCAS. Managers shared feedback from complaints from other provider locations with staff and learning was used to improve the service. Staff could give examples of how they used patient feedback to improve daily practice.

## Is the service well-led?

Good

This is the first time we rated well-led. We rated it as good.

### Leadership

**Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff. They supported staff to develop their skills and take on more senior roles.**

There was a clear management structure which staff were aware of. This meant that leadership and management responsibilities and accountabilities were explicit and clearly understood. The service was led by the chief executive

officer, medical director and head of drug development department. Senior HCA UK leaders were frequent visitors to the site and were easily accessible to local staff. The registered manager and senior clinical staff had a very strong joint understanding of the day-to-day issues in the service. Staff spoke positively of senior leaders and those leaders expressed confidence in the people who they managed. Staff were supported to develop into research and senior roles.

### Vision and Strategy

**The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them and monitor progress.**

The service had a clear vision for what it wanted to achieve and a strategy to turn it into action. The hospital's strategy aligned with the HCA UK corporate growth strategy. The services main vision was to expand and grow using a hub and spoke model, supporting oncology research trials across the provider's network and to help establish a new provider research institute with a focus on non-oncology related topics. Progress about the service goals were discussed regularly in meetings between service leads and the chief operating officer. The service reported into the provider's wider strategy committee.

### Culture

**Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work, and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.**

Staff we met were welcoming, friendly and helpful. Staff expressed high job satisfaction and it was clear from talking to staff that there was a good working relationship between staff. Staff felt supported in their work and said there were opportunities to develop their skills and competencies, which senior staff encouraged. We observed good team working amongst staff of all levels. Staff told us they were happy working at the service and felt they contributed to creating a positive work environment. Staff felt confident raising concerns to managers and appropriate action would be taken. There were Freedom to Speak Up champions across the service, to support staff in raising patient safety concerns confidentially.

### Governance

**Leaders operated effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service**.

There was a clear governance structure in place. We saw an overall schematic of how this governance system operated with its attendant committee structure. There was an executive board with committees that covered medical governance, clinical governance, information governance and patient safety, quality and risk. The Sarah Cannon Research Institute board fed into the Joint Ventures and Sarah Cannon quality, governance and risk committee which in turn reported into the wider HCA UK governance system. There was strong guidance on the scope and responsibilities of each committee and how they interacted with each other.

The Medical Advisory Committee (MAC) advised on matters such as scope of consultant practice, patient outcomes, clinical standards and implementing new and emerging professional guidance. The MAC ensured there was a process for overseeing and verifying doctor revalidation, continuing practice development and reviewing doctor employment.

Good

# Medical care (Including older people's care)

The governance of clinical trials was regulated by the medicines and healthcare product regulatory agency (MHRA). The service has regular audits conducted by the trial sponsor company to ensure trial protocols were being complied with. There was a weekly trial oversight meeting where all patients were discussed alongside trial management, staff training, study specific training, lessons learnt from sponsor audits, processes in place to support data collection and quality control.

### Management of risk, issues and performance

**Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.**

There was an overall service level risk register which included all risks to the service. Significant risks associated with the service could be escalated to the provider level risk register. All recorded risks were graded according to severity and controls were documented, with actions required before the next review date. All actions were assigned to a responsible individual. Risks were regularly reviewed. The service had plans to cope with unexpected events, including adverse reactions during procedures. There was a risk management policy and the service undertook risk assessments, for example control of substances hazardous to health (COSHH) risk assessments. An annual audit programme ensured performance was monitored and managed consistently. Regular audits were conducted by the clinical trial sponsors to monitor compliance to clinical trial protocols. The service performance was reported to the board on a quarterly basis.

### Information Management

**The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.**

The service maintained adequate and accurate source documents and trial records as per Good Clinical Practice (GCP) guidelines. The service worked to ensure that source data was attributable, legible, contemporaneous, original, accurate, and complete and that all data reported was consistent with the source documents. The service had a patient data management standard operating procedure which detailed the process for managing electronic and paper-based data, as well as other sponsor data and the security of the data. The service had a dedicated data team which oversaw the secure transfer of data from the service to the trial sponsor.

### Engagement

**Leaders and staff actively and openly engaged with patients, staff, equality groups, the public and local organisations to plan and manage services. They collaborated with partner organisations to help ensure patient needs were met.**

We saw evidence, through surveys and feedback questionnaires, that the department engaged with patients and that changes were made when necessary. There was also the involvement of patients following complaints or incidents. The service had a programme of 'nurse rounding' where patients were asked their opinion regarding important service level decisions, an example was given regarding patient opinion being sought before making the decision to wearing masks optional in clinical areas.

The service carried out staff surveys twice a year as part of the HCA UK's wider initiative to engage with staff. Results from the most recent survey conducted in October 2022 showed the top opportunities for improvement were around recognition, staff feeling a sense of belonging and retention. We saw actions taken in response to the staff feedback.

The service ensured regular communication through various channels with staff, conducted an engagement forum, staff recognition meetings, townhall meetings, opportunities to engage with senior staff and the service had an awards system to recognise colleagues who went above and beyond. The provider had taken steps to improve mental health and social wellbeing of staff, the provider introduced wellbeing webinars, one to one check-in conversation with managers and subscription for online meditation sessions.

### Learning, continuous improvement and innovation

**All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.**

Improvement and innovation were driven at a service level and staff we spoke with were passionate about driving improvement and felt positive about working in an environment which promoted innovation. Staff said they were encouraged to present ways to work which improved the patient experience.

The service had an established quality improvement plan with various projects that were due to start or already underway at the time of the inspection. Quality improvement projects considered the impact they would have on the service and on patient experience. Projects were monitored on local and provider wide level. We saw evidence of a number of examples such as; adapting the provider's electronic oncology management system to work in a clinical trial setting, introduction of more complex clinical trials, introduction of the safeguarding screening tool and improvements being made to the premises.

The service had participated in a world first cancer vaccine trial in November 2021. The service was amongst one of the world's first centres to administer a cancer vaccine as part of a longer-term global trial to see if vaccines may be an effective measure in the prevention of cancer.

The work the service conducted was a part of global efforts to trial new and existing cancer drugs in order to find new ways for effective treatment of specific tumour types. As such the service was part of a global network consisting of other clinical trial units, pharmaceutical companies and oncology centres which contributed to the scientific advancement of cancer treatment. We saw numerous examples of where work done at the centre contributed to papers published in scientific journals, additional research work being conducted, and knowledge being shared through professional and academic educational facilities. Apart from working on a global level, the principal investigators from the service worked as independent academic researchers to review patients' outcomes. We saw an example where the service reviewed the outcomes of colorectal cancer patients enrolled into a phase I clinical trial in the unit during the last 10 years and evaluated the overall response to early phase drugs and survival outcomes. The results are to be displayed in a poster in a prominent international conference in 2023.