

From: s22  
To: s22  
Subject: FW: RegConnect 24 [SEC=OFFICIAL]  
Date: Wednesday, 25 September 2024 10:17:36 AM  
Attachments: [image001.jpg](#)

Hi Team,

Please send any nominations for Sydney staff to attend regconnect24

Please return asap

Thank you  
s22

From: s22  
Sent: Tuesday, September 24, 2024 9:55 PM  
To: DUFFY, Tracey <[Tracey.Duffy@health.gov.au](mailto:Tracey.Duffy@health.gov.au)>  
Subject: Re: RegConnect 24 [SEC=OFFICIAL]

Hi Tracey,

Here is an update on the showcase from sponsors to help with additional TGA assessors.

Organisation Name	Product
s22	
s22	"Technology - two Radiology-AI solutions. a decision-support AI for chest x-rays, and a decision-support AI for non-contract head CT images. s22 2. Harrison.rad.1 <a href="https://harrison.ai/news/reimagining-medical-ai-with-the-most-powerful-large-multimodal-foundational-model-designed-to-excel-in-radiology/">https://harrison.ai/news/reimagining-medical-ai-with-the-most-powerful-large-multimodal-foundational-model-designed-to-excel-in-radiology/</a> "
s22	

s22  
Kind regards,  
s22

s22





**From:** s22  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: AI data issues [SEC=OFFICIAL]  
**Date:** Tuesday, 8 October 2024 5:49:08 PM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)

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Hi s22 and s22

Seems this one has no clear home, but most likely fits with Devices as the key issue is about AI and patient data and consent.

We would need your guidance on whether the device was approved or unapproved and take action accordingly if unapproved.

As for the using patient images for AI purposes, would your team managing the AI project be best placed to lead? RCB are not able to comment on action for that aspect.

Possible structure could be:

- This is how devices are regulated in Australia.
- Role of TGA.
- How we manage approved
- Additional background – known entity etc.
- How we manage unapproved (RCB can provide input here).
- AI project/AI considerations.

RCB happy to provide lines around approach to unapproved goods, but given that is not the key issue think it is best for Devices to lead the brief.

Happy to discuss further.

Thanks

s22

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**From:** s22 @Health.gov.au>  
**Sent:** Tuesday, October 8, 2024 2:57 PM  
**To:** s22 @health.gov.au>; s22  
[REDACTED]@health.gov.au>  
**Cc:** s22 @Health.gov.au>  
**Subject:** RE: AI data issues [SEC=OFFICIAL]

Ha! I also sent it on! We're definitely crossing paths in cyberspace

s22  
**Executive Officer to Tracey Duffy, First Assistant Secretary**  
Medical Devices & Product Quality Division | Health Products Regulation Group  
P: s22

---

**From:** s22 @health.gov.au>

**Sent:** Tuesday, October 8, 2024 2:55 PM  
**To:** s22 [REDACTED] <[REDACTED]@health.gov.au>  
**Cc:** s22 [REDACTED] <[REDACTED]@Health.gov.au>  
**Subject:** FW: AI data issues [SEC=OFFICIAL]

Hi s22 [REDACTED]  
 Below FYI - s22 [REDACTED] and my emails may have crossed paths in cyberspace  
 Regards, s22 [REDACTED]

---

**From:** s22 [REDACTED]  
**Sent:** Tuesday, October 8, 2024 1:53 PM  
**To:** s22 [REDACTED] <[REDACTED]@Health.gov.au>; NOJA, Marcelle  
 <Marcelle.Noja@health.gov.au>; s22 [REDACTED] <[REDACTED]@Health.gov.au>; JAMIESON,  
 John <John.JAMIESON@Health.gov.au>  
**Cc:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 [REDACTED]  
 [REDACTED] <[REDACTED]@Health.gov.au>; s22 [REDACTED]  
 [REDACTED] <[REDACTED]@Health.gov.au>  
**Subject:** RE: AI data issues [SEC=OFFICIAL]

Hi s22 [REDACTED]

The following information may also help in the context of requirements for data privacy in AI-enabled medical devices (which more broadly is beyond HPRG's remit). The scope of control we have over data privacy for medical devices is limited to Essential Principle 12.1:

#### **12.1 Programmed or programmable medical device or software that is a medical device**

- (1) A programmed or programmable medical device, or software that is a medical device, that is intended to make use of either or both of data and information must be designed and produced in a way that ensures that:
- (a) the safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate for the intended purpose of the device; and
  - (b) any consequent risks, or impairment of performance, associated with one or more fault conditions is eliminated or appropriately reduced; and
  - (c) the device is resilient with respect to interactions that could occur during the use of the device and that could result in unsafe performance of the device; and
  - (d) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides suitable warnings in a timely manner:
    - (i) following the disruption to services upon which the device is dependent for the device's operation; and
    - (ii) following the performance of the device being adversely affected; and
  - (e) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides a means by which the user can verify correct operation of the device; and
  - (f) if relevant to the safety of a patient, or the safety and health of the user or any other person, the integrity and quality of the data or information is maintained; and
  - (g) if relevant, the privacy of the data or information is maintained.

The device must demonstrate the privacy and data of information can be maintained but there is nothing relating to what happens to the data or information as it is not within the scope of therapeutic goods regulation – that would fall within clinical/health practice.

Further relevant points:

- Patient information is protected under the Privacy Act 1988, administered by the Office of the Australian Information Commissioner.
- Information about how the Privacy Act should be applied by health practitioners in healthcare settings can be found on the Office of the Australian Information Commissioner's website here: <https://www.oaic.gov.au/privacy/privacy-guidance-for-organisations-and-government-agencies/health-service-providers/guide-to-health-privacy>
- Salient points are mostly under [Chapter 9: Research](#) and [Health and medical research](#).

From the health and medical research page:

*In certain circumstance, the Privacy Act permits the handling of health information and personal information for health and medical research purposes, where it is impracticable for researchers to obtain individuals' consent. This recognises:*

- *the need to protect health information from unexpected uses beyond individual healthcare*
- *the important role of health and medical research in advancing public health.*

*To promote these ends, the Privacy Commissioner has approved two sets of legally binding guidelines, issued by the [National Health and Medical Research Council](#) (NHMRC). Researchers must follow these guidelines when handling health information for research purposes without individuals' consent. The guidelines also assist Human Research Ethics Committees (HRECs) in deciding whether to approve research applications. The guidelines are produced under sections 95 and 95A of the Privacy Act. The guidelines are:*

- [Guidelines under Section 95 of the Privacy Act 1988](#), which set out procedures that HRECs and researchers must follow when personal information is disclosed from a Commonwealth agency for medical research purposes.
- [Guidelines under Section 95A of the Privacy Act 1988](#), which provide a framework for HRECs to assess proposals to handle health information held by organisations for health research (without individuals' consent). They ensure that the public interest in the research activities substantially outweighs the public interest in the protection of privacy.

Hopefully this helps

Regards, s22

s22

s22, Devices Emerging Technology Section

Medical Devices Surveillance Branch

Australian Government, Department of Health and Aged Care  
Therapeutic Goods Administration

QLD State Office, 160 Ann Street, Brisbane CBD, QLD 4000

Phone: s22

PO Box 100, Woden ACT 2606

[www.tga.gov.au](http://www.tga.gov.au)

*The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

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---

**From:** s22 <[REDACTED]@Health.gov.au>

**Sent:** Tuesday, October 8, 2024 1:46 PM

**To:** NOJA, Marcelle <Marcelle.Noja@health.gov.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>

**Cc:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@Health.gov.au>

**Subject:** RE: AI data issues [SEC=OFFICIAL]

Thank you s22 I've spoken with s2 who has agreed this request can be sent to RPSD to manage, with input from MDSB on AI regulation more broadly.

I'll refer this matter to RPSD, with cc to you.

Kind regards

s22

**Executive Officer to Tracey Duffy, First Assistant Secretary**  
 Medical Devices & Product Quality Division | Health Products Regulation Group  
 P: s22

---

**From:** NOJA, Marcelle <Marcelle.Noja@health.gov.au>

**Sent:** Tuesday, October 8, 2024 2:12 PM

**To:** s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; JAMIESON, John <John.JAMIESON@Health.gov.au>

**Cc:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@Health.gov.au>

**Subject:** RE: AI data issues [SEC=OFFICIAL]

Hi s22

I think this is actually a compliance issue as this doesn't appear to be a regulated product.

We can brief on AI more broadly?

Marcelle

---

**From:** s22 [REDACTED] <[REDACTED]@Health.gov.au>  
**Sent:** Tuesday, October 8, 2024 9:51 AM  
**To:** NOJA, Marcelle <Marcelle.Noja@health.gov.au>; s22 [REDACTED]  
 [REDACTED] <[REDACTED]@health.gov.au>  
**Cc:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 [REDACTED]  
 [REDACTED] <[REDACTED]@Health.gov.au>; s22 [REDACTED]  
 [REDACTED] <[REDACTED]@Health.gov.au>; s22 [REDACTED] <[REDACTED]@Health.gov.au>  
**Subject:** FW: AI data issues [SEC=OFFICIAL]

Hi team, please see request below for an MB on the media article available at: [Emergency room medical scans used to train AI, docs suggest \(crikey.com.au\)](https://www.crikey.com.au/emergency-room-medical-scans-used-to-train-ai-docs-suggest/) (I've attached a copy of the article as well – in case the link becomes inactive).

Parli had a lot of questions about the MB, so I will contact MPS directly to request the creation of a new MB template. Can you please confirm that the following details, specifically the title and critical date, will work for you:

Title: s47G [REDACTED]  
 Minister Responsible: **Butler**  
 Group Responsible: **HPRG - MDPQD**  
 Critical Date: **30 October 2024**

Thank you  
 Kind regards

s22 [REDACTED]

**Executive Officer to Tracey Duffy, First Assistant Secretary**  
 Medical Devices & Product Quality Division | Health Products Regulation Group  
 P: s22 [REDACTED]

---

**From:** s22 [REDACTED] <[REDACTED]@health.gov.au>  
**Sent:** Tuesday, October 8, 2024 9:14 AM  
**To:** s22 [REDACTED] <[REDACTED]@Health.gov.au>  
**Cc:** s22 [REDACTED] <[REDACTED]@Health.gov.au>; DUFFY, Tracey  
 <Tracey.Duffy@health.gov.au>; HPRG Parliamentary <HPRG.Parliamentary@Health.gov.au>;  
 s22 [REDACTED] <[REDACTED]@health.gov.au>  
**Subject:** FW: AI data issues [SEC=OFFICIAL]

Hi s22 [REDACTED]

Tony has asked that we please prepare a Department initiated MB for the following media article:

[Emergency room medical scans used to train AI, docs suggest \(crikey.com.au\)](https://www.crikey.com.au/emergency-room-medical-scans-used-to-train-ai-docs-suggest/)

I've cc'd in Parli so they can get the PDR created.



Please cc Tony and I when the MB is sent up to the MO.

Cheers,

s22

[Redacted]

Executive Officer to Deputy Secretary Professor Anthony Lawler

Health Products Regulation Group  
Australian Government, Department of Health and Aged Care  
📞: s22 | 📧: s22@health.gov.au

This email comes to you from Ngunnawal Country  
Location: 27 Scherger Drive Fairbairn, Level 2

*I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.*

*The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

---

**From:** LAWLER, Tony <Anthony.LAWLER@Health.gov.au>  
**Sent:** Tuesday, October 8, 2024 9:00 AM  
**To:** MASON, Jenny <jenny.mason@health.gov.au>; s22  
[Redacted]@health.gov.au  
**Subject:** AI data issues [SEC=OFFICIAL]

Hi  
Can we please get a brief for the MO on this one

[Emergency room medical scans used to train AI, docs suggest \(crikey.com.au\)](#)  
T

**Professor Anthony Lawler** FACEM, FRACMA, FAMA, FACHSM (Hon), MBBS, BMedSci, MBA  
(Health Mgmt)  
**Deputy Secretary, Health Products Regulation Group**  
**Australian Government Department of Health and Aged Care**  
**PO Box 100 Woden ACT 2606 AUSTRALIA**

---

The Health Products Regulation Group comprises the Therapeutic Goods Administration, the Office of Drug Control, the Office of the Gene Technology Regulator, and the Australian Industrial Chemicals Introduction Scheme.

Executive Assistant s22 T: s22 | E: s22@health.gov.au  
Executive Officer s22 T: s22 | E: s22@health.gov.au

**From:** [NOJA, Marcelle](#)  
**To:** s22  
**Cc:**  
**Subject:** FW: AI data issues [SEC=OFFICIAL]  
**Date:** Wednesday, 9 October 2024 9:31:34 AM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[RE AI data issues\\_SECOFFICIAL.msg](#)

Thanks s22 – we'll discuss internally who is best to action noting we don't deal with privacy related issues and this is now going to be a general info brief on AI.

---

**From:** s22 @Health.gov.au>  
**Sent:** Wednesday, October 9, 2024 8:56 AM  
**To:** NOJA, Marcelle <Marcelle.Noja@health.gov.au>  
**Cc:** s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>  
**Subject:** FW: AI data issues [SEC=OFFICIAL]

Hi Marcelle, I note Tracey's advice below. s22 has also subsequently replied – attached – referring this back to us to progress.

Are you happy to take this one? If so, will these details work for you?

Title: s47G  
 Minister Responsible: **Butler**  
 Group Responsible: **HPRG - MDPQD**  
 Critical Date: **30 October 2024**

Thank you

s22

**Executive Officer to Tracey Duffy, First Assistant Secretary**  
 Medical Devices & Product Quality Division | Health Products Regulation Group  
 P: s22

---

**From:** DUFFY, Tracey <[Tracey.Duffy@health.gov.au](mailto:Tracey.Duffy@health.gov.au)>  
**Sent:** Tuesday, October 8, 2024 5:02 PM  
**To:** s22 @Health.gov.au>; s22 @Health.gov.au>; NOJA, Marcelle <[Marcelle.Noja@health.gov.au](mailto:Marcelle.Noja@health.gov.au)>; s22 @health.gov.au>; JAMIESON, John <[John.JAMIESON@Health.gov.au](mailto:John.JAMIESON@Health.gov.au)>  
**Cc:** s22 @Health.gov.au>; s22 @Health.gov.au>  
**Subject:** RE: AI data issues [SEC=OFFICIAL]

Team

Can we please make sure we look at requests carefully before making decisions on them. I don't think I would have had sufficient information this morning to make a decision that it should be managed by RPSD?

This request is due 30 October so we have time and should include a range of information about the product, our regulatory framework, our current review of SaMD and AI and if we find there

could be some compliance matters – we can make reference that we have referred it. There maybe other areas in the Dept or external we need to consult with.

This brief is about also educating the Minister – ie: not just compliance focused therefore there is merit in being progressed by medical devices.

We should also consider if we need to contact those who are using it to find out more to have an all encompassing brief for the Minister including the relevant State Govt?

Thanks

Tracey

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**From:** s22 [REDACTED]@Health.gov.au>  
**Sent:** Tuesday, October 8, 2024 3:55 PM  
**To:** s22 [REDACTED]@Health.gov.au>; NOJA, Marcelle  
<Marcelle.Noja@health.gov.au>; s22 [REDACTED]@health.gov.au>;  
JAMIESON, John <John.JAMIESON@Health.gov.au>  
**Cc:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 [REDACTED]  
[REDACTED]@Health.gov.au>; s22 [REDACTED]  
[REDACTED]@Health.gov.au>  
**Subject:** RE: AI data issues [SEC=OFFICIAL]

Hi Marcelle,

Is this the article that was referring to Harrison.ai and their product s22 [REDACTED]? That one is regulated and on the ARTG (and also currently have a submission to reclassify), should we include some info on that in the brief, noting that there are no explicit requirements about this in our regs?

Thanks,

s22 [REDACTED]

---

**From:** s22 [REDACTED]@Health.gov.au>  
**Sent:** Tuesday, October 8, 2024 2:46 PM  
**To:** NOJA, Marcelle <Marcelle.Noja@health.gov.au>; s22 [REDACTED]  
[REDACTED]@health.gov.au>; s22 [REDACTED]@Health.gov.au>; JAMIESON,  
John <John.JAMIESON@Health.gov.au>  
**Cc:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 [REDACTED]  
[REDACTED]@Health.gov.au>; s22 [REDACTED]  
[REDACTED]@Health.gov.au>; s22 [REDACTED]@Health.gov.au>  
**Subject:** RE: AI data issues [SEC=OFFICIAL]

Thank you Marcelle. I've spoken with s22 [REDACTED] who has agreed this request can be sent to RPSD to manage, with input from MDSB on AI regulation more broadly.

I'll refer this matter to RPSD, with cc to you.

Kind regards

s22 [REDACTED]

[REDACTED]  
Executive Officer to Tracey Duffy, First Assistant Secretary

Medical Devices & Product Quality Division | Health Products Regulation Group

P: s22

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**To:** s22 @Health.gov.au; s22 @health.gov.au; s22 @Health.gov.au; JAMIESON, John <John.JAMIESON@Health.gov.au>

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Minister Responsible: Butler

Group Responsible: HPRG - MDPQD

Critical Date: 30 October 2024

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s22

s22

Executive Officer to Tracey Duffy, First Assistant Secretary

Medical Devices & Product Quality Division | Health Products Regulation Group

P: s22

---

**From:** MASON, Jenny <jenny.mason@health.gov.au>  
**Sent:** Tuesday, October 8, 2024 9:14 AM  
**To:** KEARNS, Kylie <Kylie.KEARNS@Health.gov.au>  
**Cc:** s22 @Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HPRG Parliamentary <HPRG.Parliamentary@Health.gov.au>; s22 @health.gov.au>  
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Cheers,

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Executive Officer to Deputy Secretary Professor Anthony Lawler

---

Health Products Regulation Group  
Australian Government, Department of Health and Aged Care  
📞: s22 | 📧: s22 @health.gov.au

This email comes to you from Ngunnawal Country  
Location: 27 Scherger Drive Fairbairn, Level 2

*I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.*

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**Subject:** AI data issues [SEC=OFFICIAL]

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**Professor Anthony Lawler** FACEM, FRACMA, FAMA, FACHSM (Hon), MBBS, BMedSci, MBA  
(Health Mgmt)

**Deputy Secretary, Health Products Regulation Group**  
**Australian Government Department of Health and Aged Care**  
**PO Box 100 Woden ACT 2606 AUSTRALIA**

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Executive Assistant	s22	T: s22	E: s22	@health.gov.au
Executive Officer	s22	T: s22	E: s22	@health.gov.au