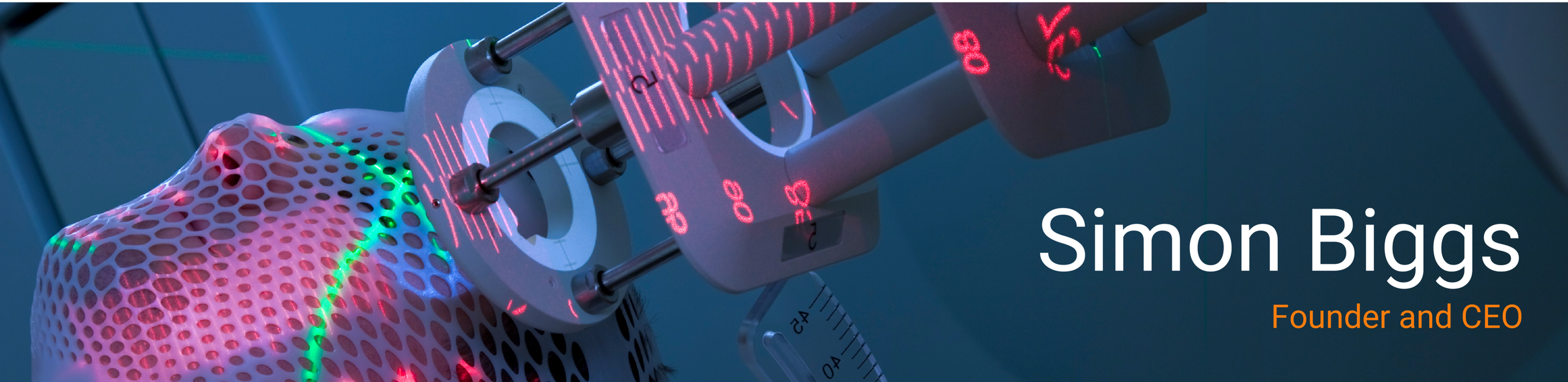
Open collaboration | OpenSaMD

A new paradigm for commercial medical device development



Simon Biggs

Founder and CEO

Who am I? Why am I here?

Far and away the best prize that life has to offer
is the chance to work hard at work worth doing
– Theodore Roosevelt

As medical physicists we get to use our maths and physics skills everyday to be a part of saving lives

When we partner and collaborate as a community we can save more lives than we ever could by ourselves

When we encode our expertise into software we supercharge our combined saving lives capacity

Open Source?

Known for Open Source

Built an open source community

PyMedPhys

Now an open source medical device?

Open Source?

But doesn't it have problems?

How do you make money when you give it away?

Who's liable?

Do I have to learn Python to use the tools!?

Why should I use it when it doesn't have the backing of a sustainable buisness?

What about regulation?

How is it secure when the code is all available?

How do you protect the privacy of my patients?

How do you protect the IP?

How can you assure quality when people all around the world can contribute code?

How do I get support?

Open Source?

What problems are you most concerned about?

Open Source?

Let's address these issues...
But first, let's see what it can bring
for our patients and us

Open Source is eating AI

GPT 2 — 6 months

2019 Feb

OpenAI announced GPT-2
It wasn't released, thought to be too dangerous

2019 August

Two masters students
Open source versions of the model made and released

2019 November

OpenAI released their model
They then made theirs open source too

Liberal utilisation of: https://lspace.swyx.io/p/open-source-ai

Open Source is eating AI

GPT 3 — 10 months

2020 May

OpenAI releases GPT-3 in closed beta

2020 September

Microsoft gets exclusive GPT-3 license

2021 March

Open source version by EleutherAI

2022 May

Open source version by Meta (Facebook)

Liberal utilisation of: https://lspace.swyx.io/p/open-source-ai

Open Source is eating AI

Text-to-image — 26 months

2020 June

OpenAI teases Image GPT

2021 January

DALL-E from OpenAI

2022 March

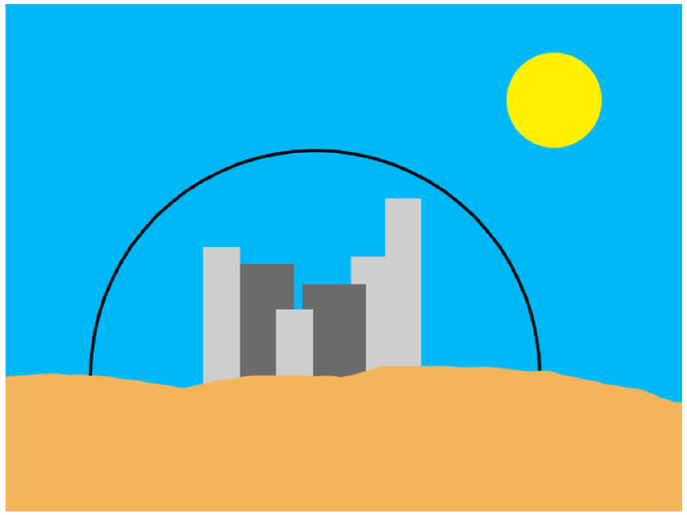
Closed Midjourney version

2022 August

Open source version by Stability AI

Liberal utilisation of: https://lspace.swyx.io/p/open-source-ai

Open Source is eating AI



+

A distant futuristic city full of tall buildings inside a huge transparent glass dome, In the middle of a barren desert full of large dunes, Sun rays, Artstation, Dark sky full of stars with a shiny sun, Massive scale, Fog, Highly detailed, Cinematic, Colorful

https://simonwillison.net/2022/Aug/29/stable-diffusion/ and
https://www.reddit.com/r/StableDiffusion/comments/wzlmty/its_some_kind_of_black_magic_i_swear/

Open Source is eating AI

Community takes the wheel

> Sufficiently advanced community is indistinguishable from magic
> – Shawn Wang

Liberal utilisation of: https://lspace.swyx.io/p/open-source-ai

Open Source is eating AI

DreamBooth: Fine Tuning Text-to-Image Diffusion Models for Subject-Driven Generation

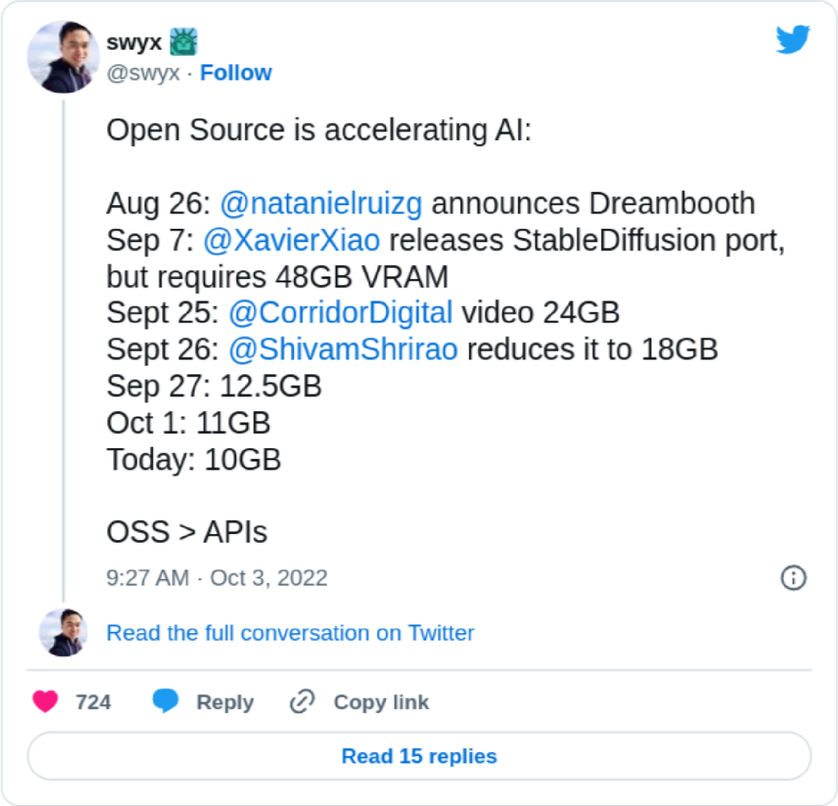
Nataniel Ruiz Yuanzhen Li Varun Jampani Yael Pritch Michael Rubinstein Kfir Aberman

Google Research

It's like a photo booth, but once the subject is captured, it can be synthesized wherever your dreams take you…

Liberal utilisation of: https://lspace.swyx.io/p/open-source-ai

Open Source is eating AI



Liberal utilisation of: https://lspace.swyx.io/p/open-source-ai

Open Source Benefits

Business development

Strategic partners through user innovation

Software development

Find bugs fast

- **edge case data** for AI model failure modes

Get bug reports for free

Get code contributions for free

Explore design and implementation

- AI **model innovation**

Recruit and hire more effectively

Product management

Identify customer requirements more readily

Explore new market segments more cheaply

Let users **explore feature space** for you

Let users explore alternatives at no costs

Support

Get help with self-help services

Reduce overall support load through self-help

Feed self-help services into commercial documentation

https://github.com/dirkriehle/coss-course/raw/main/Generated/Lecture%20slides/COSS%20C03%20-%20Commercial%20Open%20Source.pdf

What about radiotherapy?

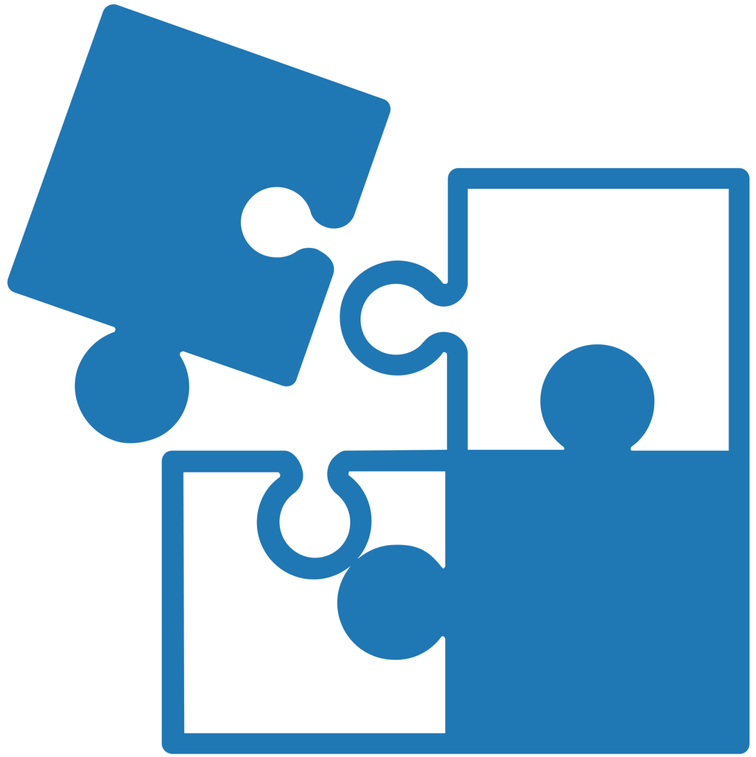
Discussion

Can we see the same impact of AI + open source + community in radiotherapy?

What do we need to do?

How can we make the magic of AI + open source + community benefit our patients?

What's missing?



TGA on in-house software

"If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device."

[Unless it is excluded or exempt]

Therapeutic Goods (Medical Devices) Regulations 2002, Part 3, Division 3.1—Medical device classifications, Section 3.3 Principles for applying the classification rules, item (5)

[In-house software]

supply includes:
... application in the treatment of a person.

Therapeutic Goods Act, Chapter 1, Part 3

NB I'm **not** a regulatory consultant

Open regulation

OPENREGULATORY

https://openregulatory.com/

Started in 2020

Templates

For ISO 13485, IEC 62304, ISO 14971 and IEC 62366

ARTICLES > GETTING STARTED >

Updated November 22, 2022

Start Here: The Blueprint for Certifying Medical Software

Dr. Oliver Eidel

Our free and open-source templates are what made us famous!

Download them for free and get your compliance done, no strings attached. Our templates currently cover compliance for ISO 13485, IEC 62304, ISO 14971 and IEC 62366.

Business Model

No current OpenSaMD is for-profit

TIDEPOOL

https://www.tidepool.org/

Project InnerEye — Microsoft

> InnerEye is a research project from Microsoft Health Futures ...

https://www.microsoft.com/en-us/research/project/medical-image-analysis/

Business Model

Open source version

Not for clinical use

Free for research use
Free for clinical trial use
Free for education use
Free for audit use

AGPL license for retaining competitive advantage

Regulated version

Paid subscription for **clinical use**

Clinical enterprise support
Clinical post-market surveillance

Towards OpenSaMD

https://github.com/RadiotherapyAI/rai

main | Go to file

SimonBiggs ··· ✓ yesterday

View code

README.md

`rai`, RadiotherapyAI's non-clinical open

https://docs.radiotherapy.ai

Radiotherapy AI's QMS and TechDoc

Radiotherapy AI's Quality Management System and Technical Documentation. Built on top of GitHub and `git`, OpenRegulatory templates, and Jupyter Book.

All source for the Medical Device, the Quality Management System, and the Technical Documentation are available at https://github.com/RadiotherapyAI/rai.

RAi | Quality

Every line of code peer-reviewed

sjswerdloff approved these changes on Sep 21 — View changes

rai/dicom/uid.py

```
35  35   RAI_IMPLEMENTATION_VERSION_NAME = f"rai-v{__version__}"
36  36
37  37   RAI_CONTOURS_IMPLEMENTATION_CLASS_UID = (
38     -     f"{_RAI_INTERNAL_ROOT_UID}{_RAI_CONTOURS_PRODUCT_ID}.{__version__}"
    38 +     f"{_RAI_INTERNAL_ROOT_UID_PREFIX}{_RAI_CONTOURS_PRODUCT_ID}.{__version__}"
```

sjswerdloff on Sep 21 — Collaborator

should be ok if `__version__` is semver and doesn't ever contain .0#.

Reply...

Resolve conversation

RAi | Quality

Every change is covered by continuous integration testing suite

```yaml
      # =======
      # PyRight
      # =======

      - name: Run PyRight
        if: matrix.task == 'pyright'
        run: |
          poetry run pyright

      # ======
      # PyTest
      # ======

      - name: Run PyTest
        if: matrix.task == 'pytest'
        run: |
          poetry run pytest --pylint --doctest-modules

```

Run PyTest

```
▶ Run poetry run pytest --pylint --doctest-modules
============================ test session starts ============================
platform linux -- Python 3.10.6, pytest-7.1.3, pluggy-1.0.0
rootdir: /home/runner/work/rai/rai
plugins: pylint-0.19.0, anyio-3.6.1
collected 26 items
--------------------------------------------------------------------------------
Linting files
........................................
--------------------------------------------------------------------------------

rai/__init__.py .                                                        [  3%]
rai/__main__.py .                                                        [  7%]
rai/_paths.py .                                                          [ 11%]
rai/_version.py .                                                        [ 15%]
rai/_cli/__init__.py .                                                   [ 19%]
rai/_cli/_paths.py .                                                     [ 23%]
rai/_cli/docs.py .                                                       [ 26%]
rai/_cli/propagate.py .                                                  [ 30%]
rai/data/__init__.py .                                                   [ 34%]
rai/data/download.py .                                                   [ 38%]
rai/dicom/__init__.py .                                                  [ 42%]
rai/dicom/_inheritance.py .                                              [ 46%]
rai/dicom/append.py ..                                                   [ 53%]
rai/dicom/typing.py .                                                    [ 57%]
rai/dicom/uid.py .                                                       [ 61%]
rai/mask/__init__.py .                                                   [ 65%]
rai/mask/convert.py .                                                    [ 69%]
rai/mask/test_convert.py ...                                             [ 80%]
rai/metrics/__init__.py .                                                [ 84%]
rai/metrics/dice.py .                                                    [ 88%]
rai/metrics/test_dice.py ...                                             [100%]
```

RAi | Privacy

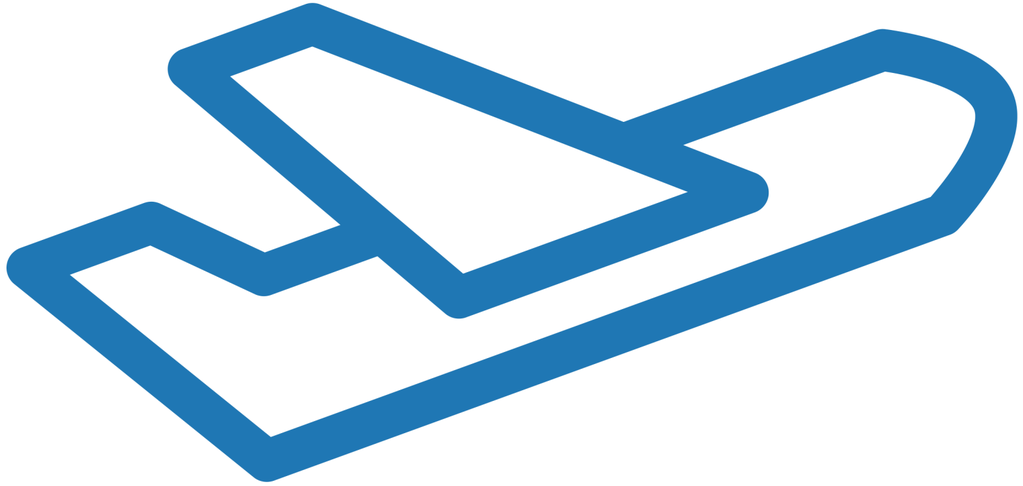
Software runs entirely on local hardware

- Patient information is not submitted offsite during software utilisation
- Data for model updates is DICOM header anonymised and submitted to RAi separately under a data sharing agreement
- Private model data does not leave the jurisdiction of Australia and is not provided to any third parties outside RAi

Building an "Airport"

Building an "Airport"

And we want to help **your** planes fly!



Overcoming the issues

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- Do I have to learn Python to use the tools!?
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- How can you assure quality when people all around the world can contribute code?

Build the community

And save more lives than we ever could alone

Sufficiently advanced community is indistinguishable from magic
– Shawn Wang

If this excites you, let's chat

simon@radiotherapy.ai