Towards an Open Source AI Medical Device

Creating a new paradigm for commercial software

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Disclosure

Both authors of this presentation are co-founders of Radiotherapy AI, a company devoted to creating a commercial product that adheres to the philosophy detailed within this presentation.

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The Problem

AI is rapidly advancing - but where is the benefit to the patient?

AI needs global insights and global edge case coverage

Radiotherapy software is opaque, hard to test, and hard to fix

The Solution

- Build it together: Medical Physicists, researchers, RTs and clinicians all around the world
- Build it in the open
- Show that AI software built in the open is the best way to remain on the crest of innovation - sharing ideas, training on a wider variety of datasets
- Show that a company making an open source Medical Device can still be viable, successful and safely regulated

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The Impact

- Light up the path for Medical Device companies to join this new paradigm of Medical Device development, changing from:
  - Opaque ➡ Transparent
  - Silos ➡ Build collaboratively with input from users around the world
  - Lagging ➡ Leading the way
- Save more lives than any one of our products or projects could ever hope to achieve by itself

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Regulatory Support

OpenRegulatory, Diapson Consulting, ANDHealth, TGA, and Cicada Innovations

ANDHealth
Australia's National Digital Health Initiative

CICADA INNOVATIONS

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

OPEN REGULATORY

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TGA Classification | Class IIb

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

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)

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Where we are now

https://github.com/RadiotherapyAI/rai

https://docs.radiotherapy.ai

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Where we are going (Lord willing)

2022 December

Initial TGA submission

2023 February

National clinical trial

2023 October

TGA regulatory approval

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Let's do this together