A short presentation..

Client: N/A
Client Project Name: N/A
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Prepared for: N/A
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Checked by: L James (THAY Medical).
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Revision History

Revision	Description of Change	Revision Date
A	New Document	23rd September 2016

Document Approvals

Name: _____ Signed: _____

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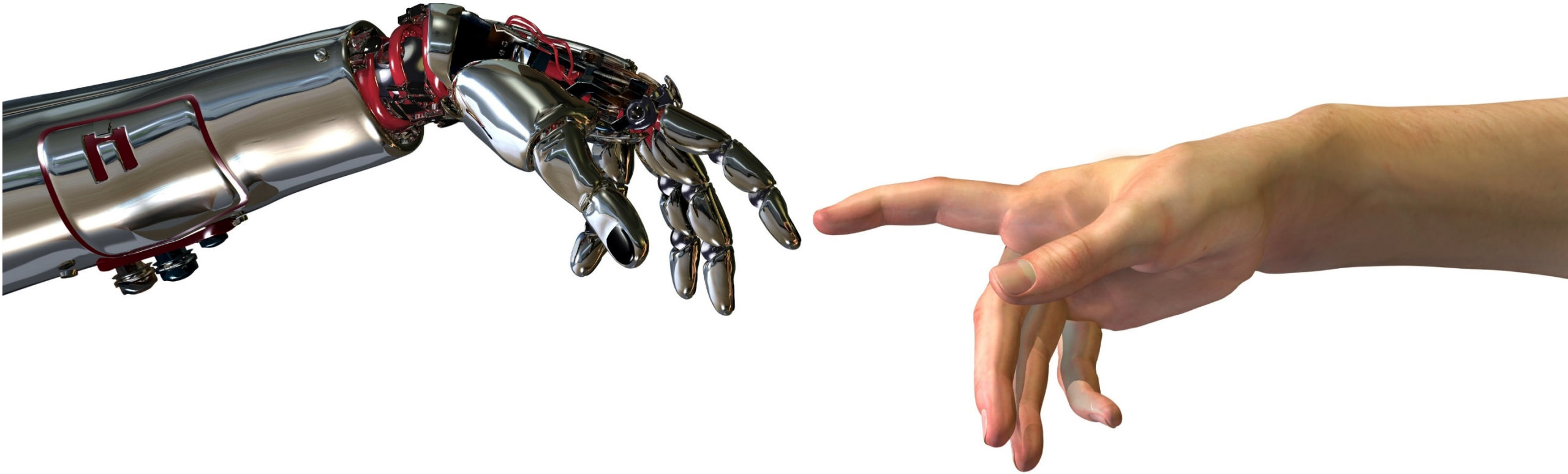
A short introduction..

Greg Thay
Managing Director



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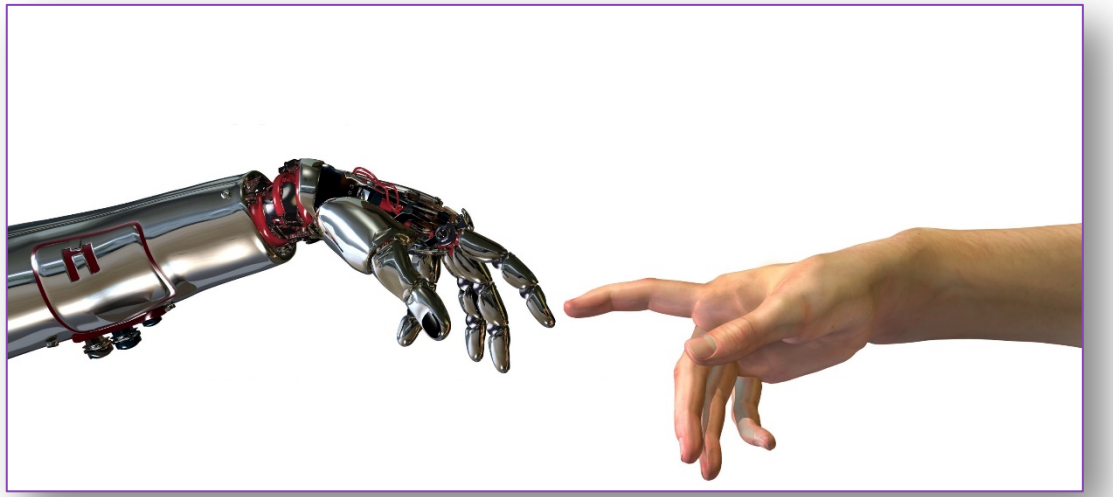
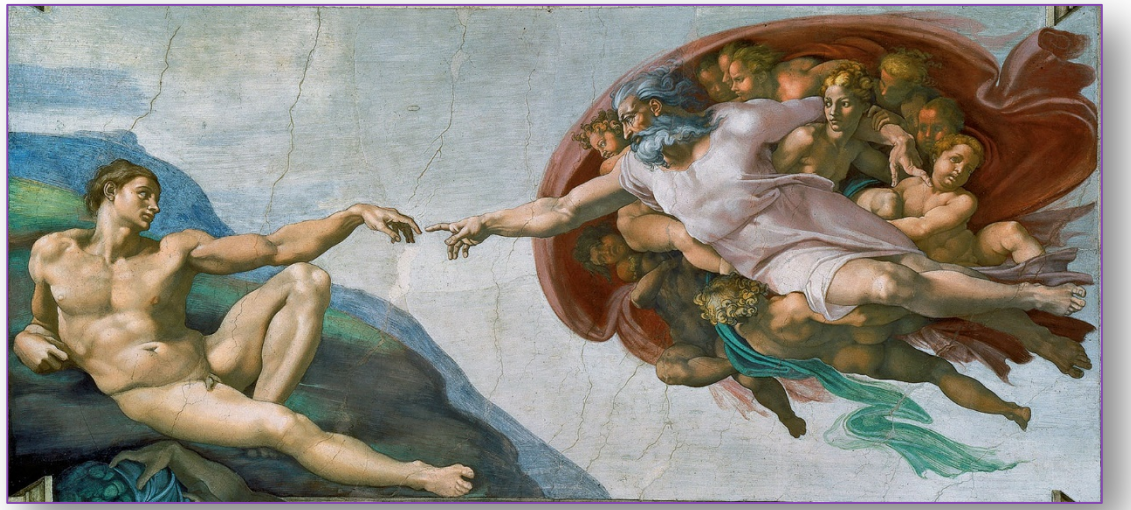
Where does the image come from?

"The creation of Adam"





To add a modern twist to Michael Angelo's "Creation of Adam" (as seen at the Sistine Chapel), we use the image of a robot hand and a human hand instead of God's hand and Adam's hand.

Where God was breathing life into Adam, we see ourselves as breathing life into future medical products. At some point in the future it may be the human hand breathing life into a robot hand..

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So why are we here today?

To introduce to you all the science of human factors and usability – which is our company's focus.

Why?

Because for any medical device, an understanding of its use safety is now a global requirement.

AND

If you want not to just produce a *good* product, but a GREAT product, you have to make it –

- **Easy to use.**
- **Clinically effective and minimal in management.**
- **Suited to the intended user.**
- **Safe for all intended users.**

This is the focus of THAY Medical.

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Introducing THAY Medical

A few things about THAY Medical:

- Formed in 2014 to focus on the subject of medical device human factors engineering and usability.
- Only focused on medical devices for the medical, biotechnology and pharmaceutical industries.
- Is an ISO13485 certified, independent human factors engineering consultancy.
- Located in Blandford Forum, Dorset, England. Approx. 2 hours drive/train from Cardiff, Wales.
- Has two offices – the Main Office (see photo right) and a separate Testing & Development Facility nearby.
- Are a team of human factors engineers, project managers, technicians and consultants.

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What we do:

THAY Medical are a human factors engineering consultancy. We offer the following services:

- Usability Engineering
- Global Human factors Testing
- Medical Device Testing
- Project Management
- CE Marking
- Medical Device Design
- Market Research
- Quality Control

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Where we work:

THAY Medical is able to evaluate medical devices pretty much anywhere. There are some countries we cannot due to political agreements, but users can be evaluated in most countries upon request. We currently focus on performing evaluations in four main countries most frequently:

- UK & Ireland
- France
- Germany
- USA
- Australia

In addition we have the capability to perform evaluations in Spain, Italy, Poland, Brazil, Canada, South Korea and New Zealand.

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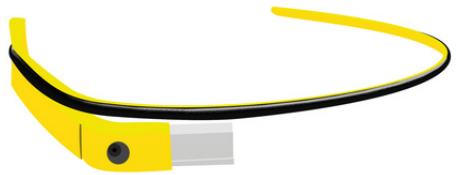
What medical devices have we experience on:

THAY Medical only focuses on medical devices, but this is quite a diverse industry. Our experience so far includes the following devices:

- Infusion pump systems
- Multiple pen injectors & auto-injectors
- Digital injection devices
- A plasmapheresis machine
- A vision enhancer
- Infusion accessories
- Wound dressings & Implants
- Lancets
- A personal lubricant (!)



And the list will continue to grow…

But we cannot show you any pictures as some of these devices are not launched yet!

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What is Usability? What is Human factors?

Human factors is the -

“Discipline of applying knowledge of human behaviour, methods for analysis, test and evaluation techniques that lead to outcomes including usability, ease of use, and safe operation within the capabilities and limits of the human operator.”

Human factors engineering is the term used for applying a human factors method to engineering and developing a product – a medical device.

Human factors engineering originated in the aerospace industry and has been included in medical device design processes since it aims to focus upon the human elements that affect the safe operation of a product.

Human factors engineering processes interact with risk management processes (ISO 14971:2012 for example) so that use safety is paramount in the risk process.

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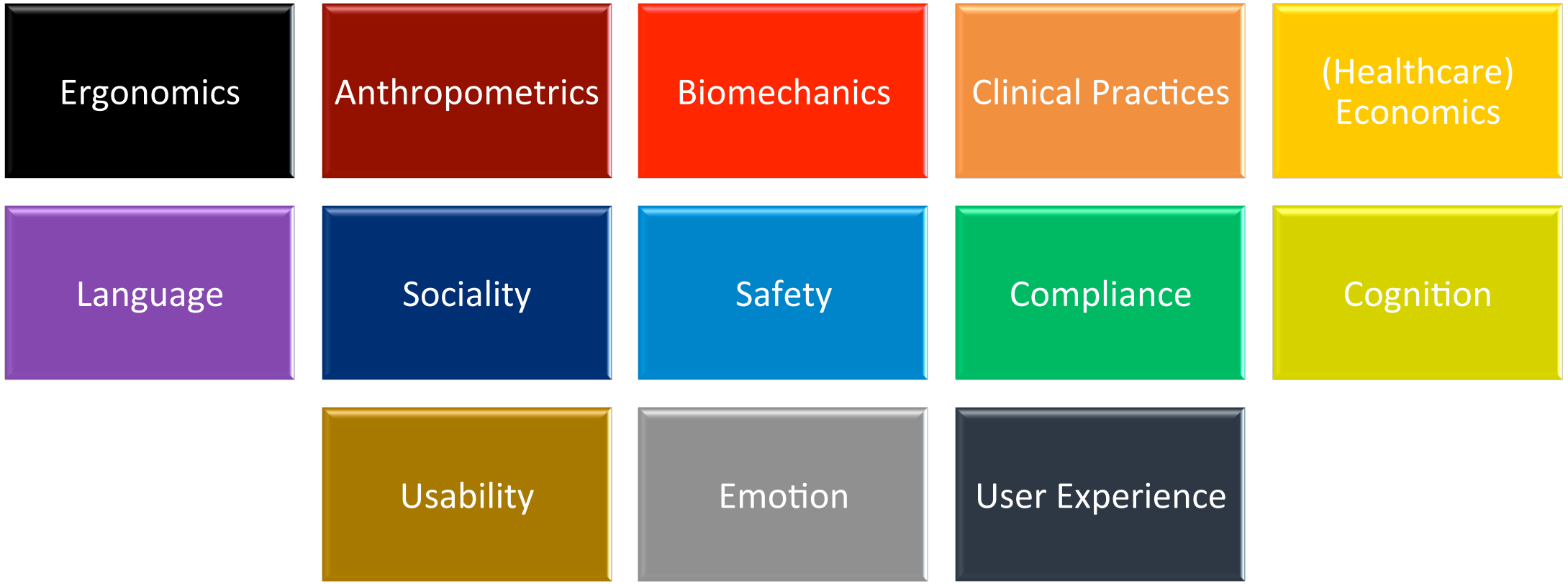
What is Human factors?

Key areas that define human factors:



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Potentially incorrect usability.

Quick case study – packaging!

Child Proof caps on pill containers.

Safety element: protects children from access to pill container contents – medicines that could harm them.

Fine for: Most users, who are adult, able bodies and have no dexterity limiting conditions.

Not good for:

1) adults with dexterity limiting conditions such as arthritis.
2) adults with hand based injuries.
3) drugs that are required to be used by children!
4) Rescue pills – where quick access is required.
5) Older adults with less strength.
6) Older adults with cognitive difficulties.

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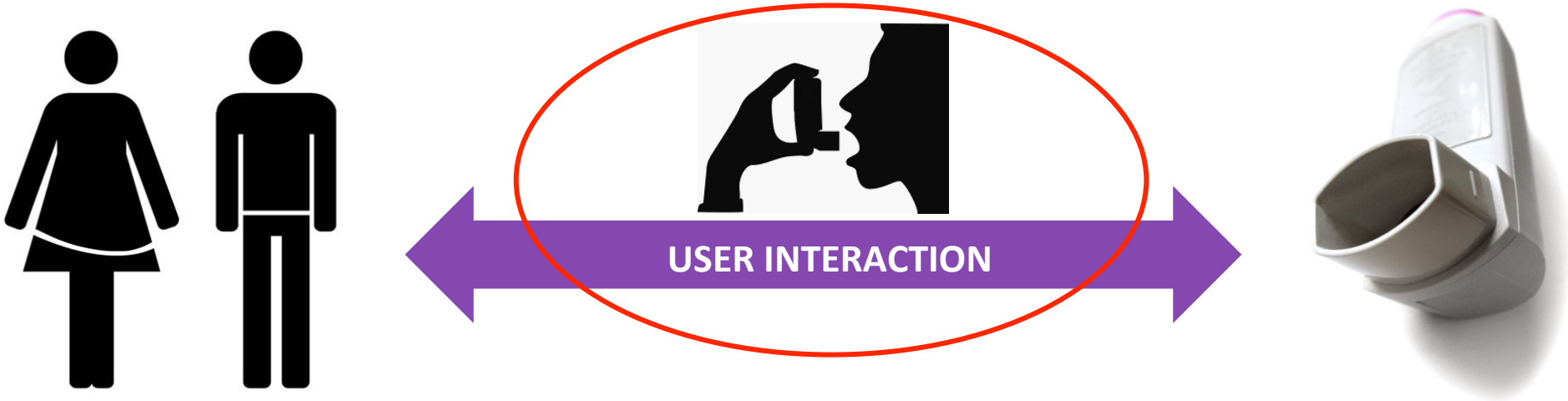
What is Usability Engineering?

"Usability Engineering" is defined as the **"APPLICATION OF KNOWLEDGE ABOUT HUMAN BEHAVIOUR, ABILITIES, LIMITATIONS, AND OTHER CHARACTERISTICS TO THE DESIGN OF MEDICAL DEVICES (INCLUDING SOFTWARE), SYSTEMS AND TASKS TO ACHIEVE ADEQUATE USABILITY."**

IEC 62366-1:2015, SECTION 3.17

It aims to validate the process of successful **user interaction**.



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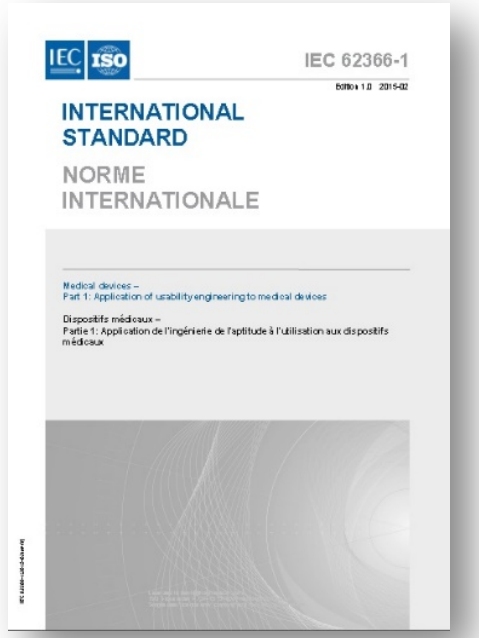
Usability Engineering has a process?

The Usability Engineering process -



- Is now guided by an International standard IEC 62366-1: 2015.
- Replaced the previous standard IEC 62366: 2007.
- Aligned with the US-based FDA guidance for "*Applying Human Factors and Usability Engineering to Medical Devices*", which is mandated in the USA if you want to gain a pre-market authorisation from the FDA.
- Is an International standard which can be used anywhere in the world, and is recognised by the US-based FDA and other global regulatory authorities.
- Is currently the industry standard for medical devices or performing usability engineering, but is not mandatory to use for CE Marking a medical device.

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Why do medical devices need to include usability?

Medical devices need to include usability -

- To ensure that medical devices are **usable** by all users, including healthcare professionals and patients.
- To ensure that medical devices are **safe** to use by all users.
- To ensure that medical devices are **suited** to their intended use and environment.
- To generate confidence in the devices **ability** to withstand its lifecycle's expected use.
- Without usability data, a CE Mark on a medical device may be difficult to achieve.

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What is Bad Usability?

Some examples of not so great human factors and usability!

Confusing directions

Opening packaging

Mislabelling

Understanding symbols

We all find examples of products that haven't considered the user elements in their design.

With the above examples there is often significant risk with the outcome of the wrong instruction or action.

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A focus on Human Factors Innovation:

THAY Medical recently exhibited at the Diabetes UK Professional Conference in Glasgow, UK. The aim was to test out some research theories with Diabetes Nurses and Consultants. The event was a success and the data shows there is much future innovation happening at all levels of patient care and management.

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Services we currently perform for customers:

THAY Medical can help you perform the following to assist with your medical device development and post-launch market surveillance:

Usability Engineering	Project Management	Human Factors Testing	Ethnography	Concept Design User Research	Comparative Usability Studies	Use Specification
Usability Risk Assessment	Risk Management Planning	User Interface Design	User Interface Specification	Medical Market Research	Medical Device Testing	Formative Usability Testing
Summative Usability Testing	Task Analysis	Outsourced Quality Control	Packaging Design	Labelling	User Manual Design	Patient Information Leaflets
Readability Studies	CE Marking	Regulatory Affairs	Translations	Human Factors Engineering	Heuristic Analyses	Clinical Evaluation Reports

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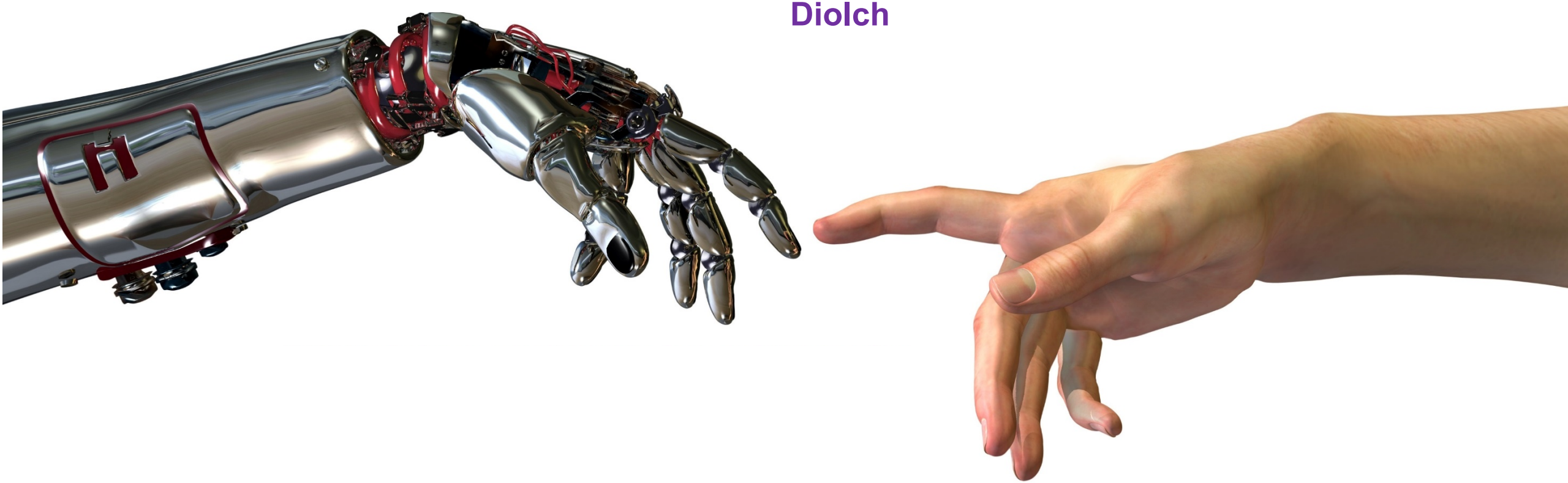

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