

The Clinical Auditor's Perspective: To Err is Human



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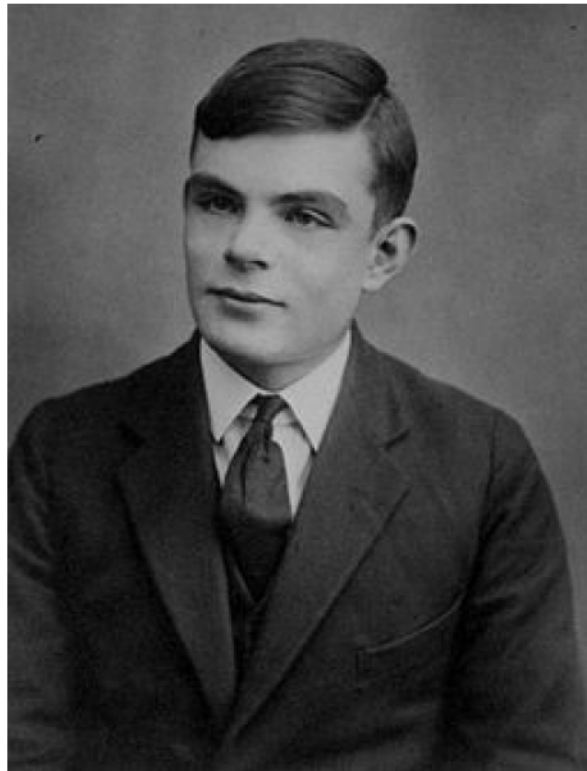
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Introduction

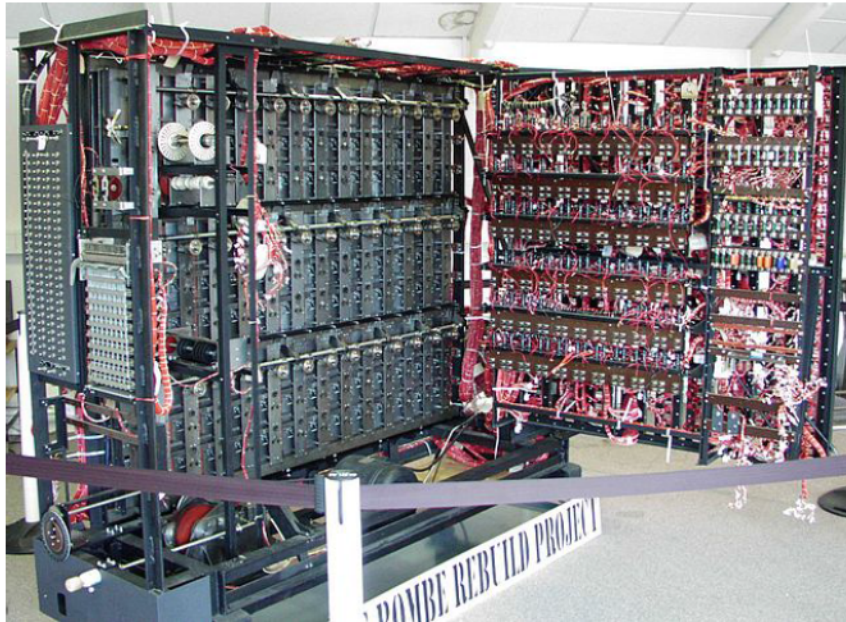
Humans

are CREATIVE.

Creative Human



Creative Human Creation: Computer



- Rebuild of the British Bombe
 - Bletchley Park, UK
 - Original 1940

Image from the Bombe Rebuild Project

Who Knew?

- Ubiquitous
- Part of the daily landscape
- Trustworthy
- Our friends
- Our team mates

75 Years Later: Computer Trust

- General public computer trust
- Stronger than human trust

Complete Computer Trust



Complete Computer Trust

- Under experimental conditions:
 - Humans trust instructions from an automated source over a human source
 - Backed up by fMRI

Misguided Computer Trust



- In Emergencies, Should You Trust a Robot?
- Emergency guide robot
- Mock building fire
- Unreliable
- Broken

Georgia Institute of Technology

Complete Misguided Computer Trust

- “People seem to believe that these robotic systems know more about the world than they really do, and that they would never make mistakes or have any kind of fault.”

Complete Misguided Computer Trust

- “In our studies, test subject followed the robot’s directions even to the point where it might have put them in danger had this been a real emergency.”
 - Alan Wagner, senior research engineer

Complete Misguided Computer Trust

Death by GPS



Getty Images/ Universal History Archive

Complete Misguided Computer Trust



Fatally Stranded

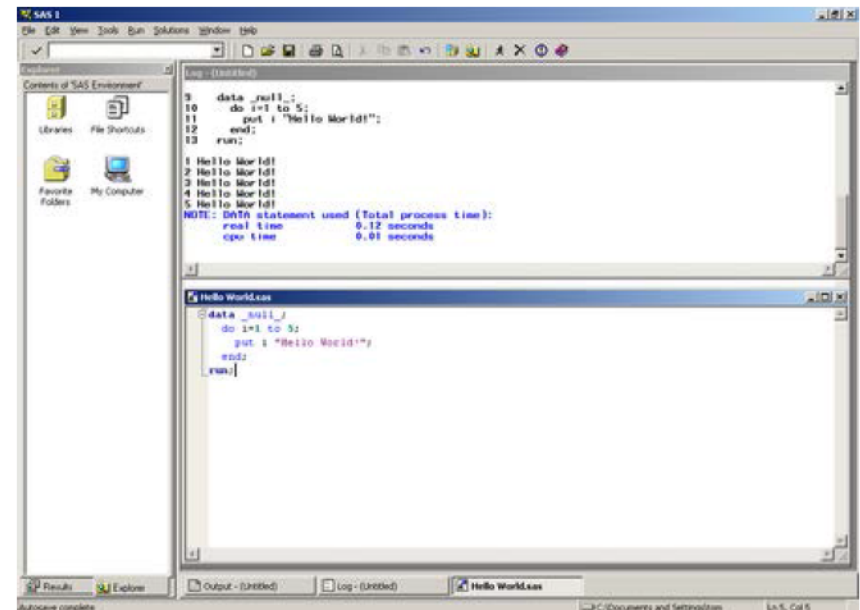
The Jarbidge Mountains of Nevada, where the Chretiens got stranded.
Chris M. Morris

Computer Trust

Clinical Research

Clinical Research Computer Revolution

- The Giant Timeline Leap
 - Hand calculations for data analyses
 - Computer analysis of data

A screenshot of the SAS software interface. The main window shows a SAS program with the following code:

```
9 data _null_;  
10 do i=1 to 5;  
11 put i "Hello World!";  
12 end;  
13 run;
```

The output window displays the results:

```
1 Hello World!  
2 Hello World!  
3 Hello World!  
4 Hello World!  
5 Hello World!
```

Below the output, a note indicates the execution time:

```
NOTE: DDTN statement used (Total process time):  
real time 0.12 seconds  
cpu time 0.01 seconds
```

The interface also shows a file explorer on the left and a status bar at the bottom.

Clinical Research Computer Revolution

- Electronic Data Capture
 - Hand input of data by humans
 - Automatic data input from machines



Clinical Research Managerial Computer Trust

- Computers are trustworthy
- Computers are expeditious
- Computers control the process
- Push the work down

Computers are the Focus, Humans are Secondary

What could possibly go wrong?

A View from the Field: Clinical Auditing

- Clinical auditors check procedures and data to ensure that clinicians (or other data generators) and their staff
 - Follow the:
 - Regulations (Rules for experimenting on humans)
 - Protocols (Documentation of the experiment)
 - Additional procedures (Data entry)

Auditors Look for Inappropriate Computer Trust

- The computer did it
- If its on the internet it must be right

Inappropriate Computer Trust Clinical Auditing Examples

- Human safety monitoring
 - Creatinine clearance
 - Blood pressure
- Data Changes
 - The dreaded global changes
- Human inattention
 - Neglect in uploading randomization code changes

Inappropriate Computer Trust/Controls

- Apple's Research Kit
 - Crowdsourcing subject recruitment
 - Technology invited the errors rather than controlling them

Appropriate Computer Trust

- Humans create computers
- Humans program computers
- Humans use computers
- Computers are just tools

Creating Trust and Productivity in the Workplace

OXYGEN

GOOGLE'S OXYGEN

- Work is personally meaningful
- Clear goals
- Dependable team mates
- Psychological safety

Curious Humans Create

- The team that broke the Inigma machine had:
 - Personally meaningful work
 - They had clear goals
- But Turing's ideas were individual and the team was failing
- The team's productivity increased when
 - They could depend on one another
 - They had psychological safety

Human Community

- How does your organization inspire creativity?
- Is your work personally meaningful?
- Do your teams have clear goals?
- Can you depend upon your team mates?
- Do you have psychological safety?

Questions?



