

The Role of a Project Programmer within GSK

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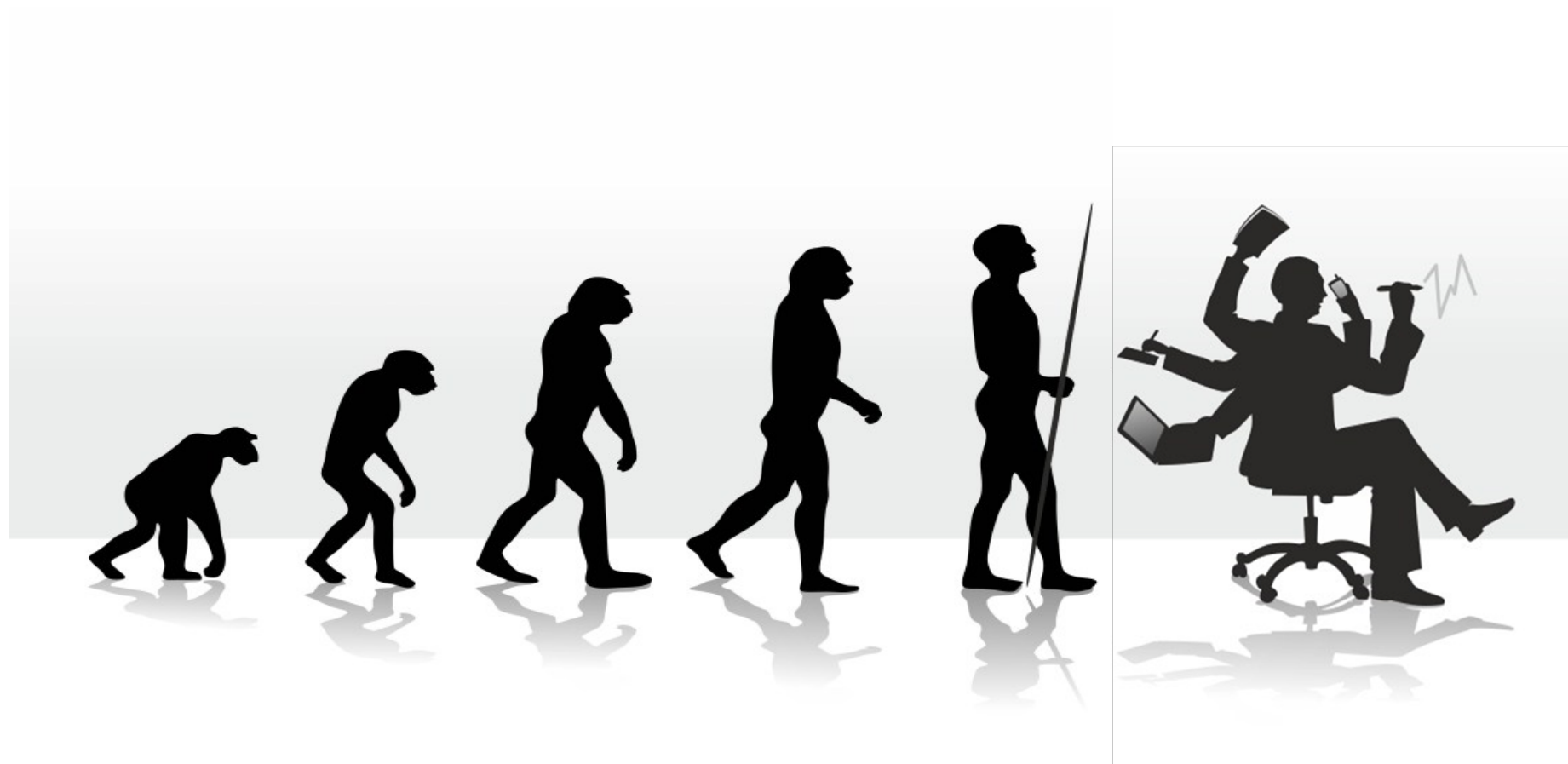
PhUSE 2018, Frankfurt

❖ Could all of you please stand.

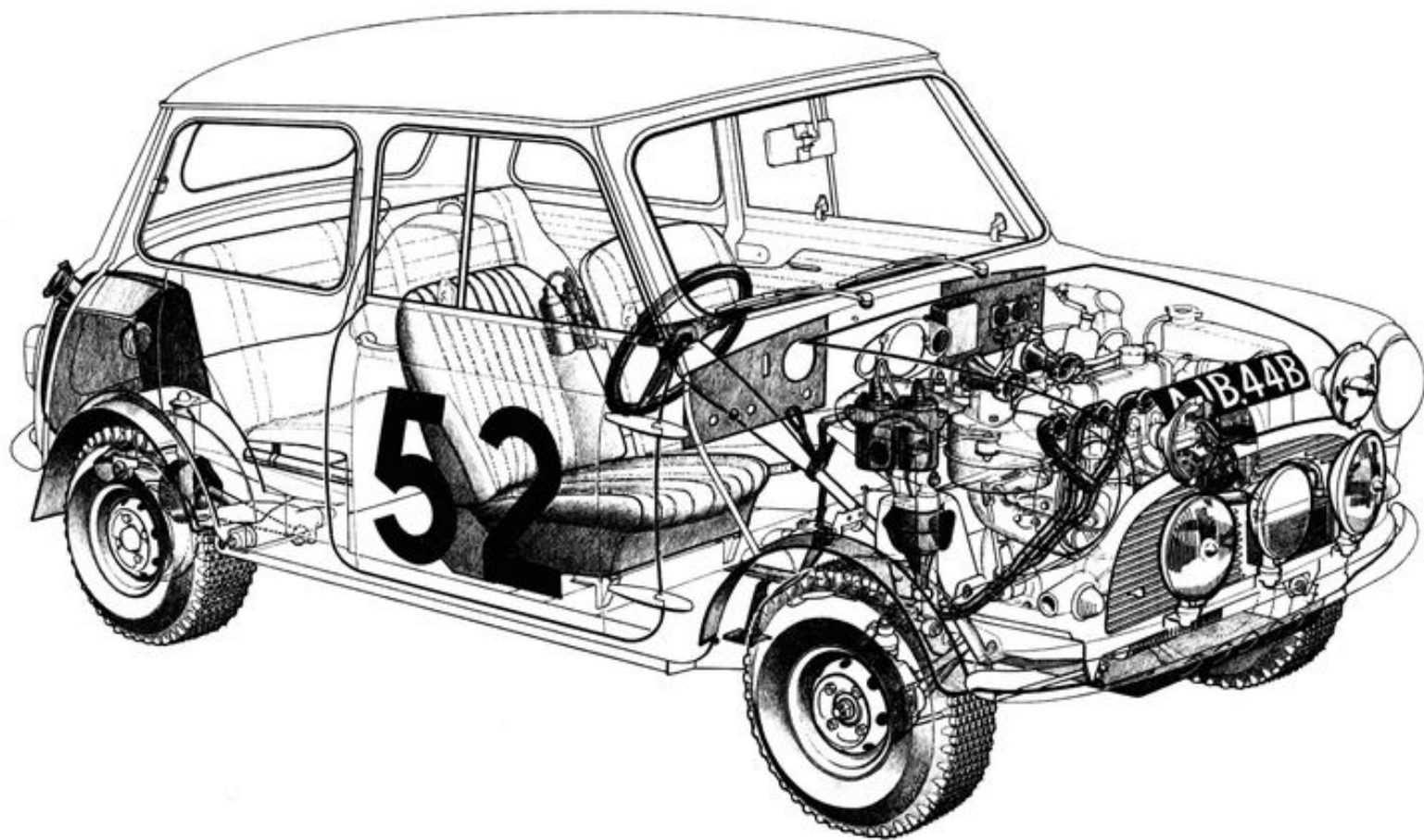
❖ Please **sit** down if the answer is **no** to the following questions;

1. Are you a programmer leading a clinical project?
 2. Alongside your lead programmer activities, does your role cover either;
 - Defining the data strategy across studies
 - Leading programming activities for submissions
 3. Are you called a project programmer/equivalent?
 4. Is this a formally recognised role in your company (independent of the statistician)?
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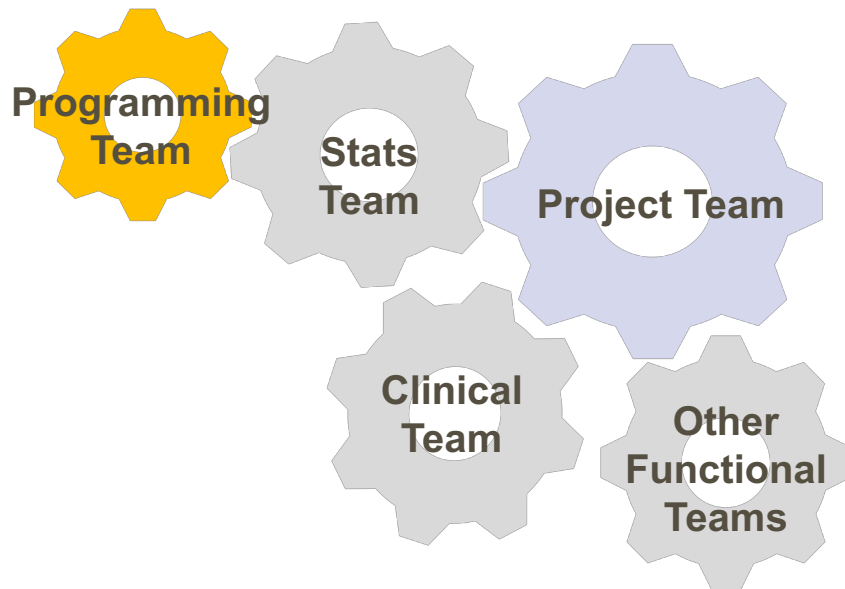
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- ❖ A **standalone** Clinical Programming **department** at GSK was formed in 2013 to support the evolving regulatory requirements and technical expertise required to **deliver clinical projects** and **regulatory submissions**
 - ❖ The formation of the department provided the opportunity and a **springboard** for programmers to become exceptional technical, operational and **strategic leaders** with a voice at the project level.
 - ❖ This presentation covers the **implementation** and **challenges** in **formalisation** of the project programmer role
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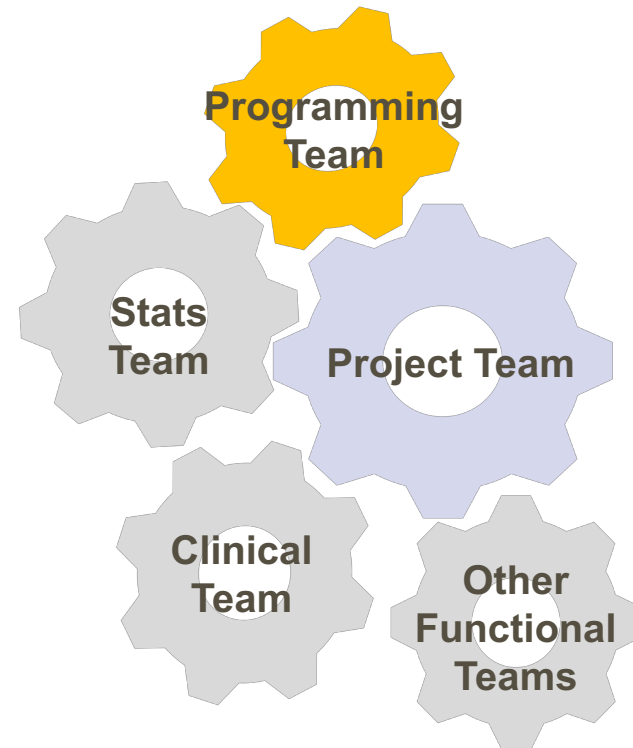




Current State



Future Vision



Formalisation of the role of Project Programmer



- ❖ Initiative for the role was **endorsed** from senior leaders
 - ❖ A team of established programmers, sponsored by the Clinical Programming Leadership Team (CP LT), shared their **experiences** of **leading projects** across the various therapeutic areas.
 - ❖ The CP LT then set the **vision** and direction of travel for the Project Programmer role.
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- ❖ To understand existing awareness of the role a survey was conducted
 - 220 responders across various key functions
 - 50% were aware of their Project Programmer

 - ❖ Two major deliverables identified to support the Project Programmer role because of the survey were:
 - **Specification/Expectations Document** to ensure alignment of expectations and consistency in application across the Clinical Programming function.
 - **Training and Development Curriculum**, facilitating capability development tailored to individual need.
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Leadership and Accountability of programming project deliverables

Define submission data strategy

Exemplar technical leaders

Drive Programming Data Strategy

Champion solutions and ensure consistency across a project

Excellence in Project management

Embed compliance to reporting standards

Accurately forecast resource and budget estimations

Proactively manage CRO relationships to ensure high-quality deliverables

Influence and Network at the project level

- ❖ The **aspiration** is to have a Project Programmer for all projects.
 - ❖ Currently **assigned** to high **priority** assets based
 - ❖ Material formalizing the role for Clinical Programming and Project Teams put in place, outlining **expectations / value** that is anticipated
 - ❖ A Project Programmer **forum** has been initiated
 - ❖ **Progress** will continue to be monitored through a second survey
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- ❖ **Implementation** of a new role within a large organisation comes with its challenges.
 - Ensuring the role is fully **embraced** within the statistics and programming lines. The **partnership** between **statisticians** and **programmers** is **critical** for successful execution at the study and project level.
 - **Awareness** of the role outside of the statistics and programming function.
 - Resistance to change, the **nature** of many programmers is a preference to **program** and input into **technical** solutions.
 - **Identifying** staff with the appropriate level of **experience** and **skill**
 - ❖ This is a **journey** that is going to take time to achieve at the desired level.
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- ❖ With the introduction of a more formal role and effective embedding, it is anticipated that the **visibility** of programmers within the project team will be increased and lead to greater **awareness** of the **vital contributions** made by Project and Study Programmers from early development through to **submission**.
 - ❖ The role also provides clear **accountabilities** for the overall **leadership** of **programming deliverables** and offers greater career **opportunities** for **aspiring** programmers.
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Thank You !

Questions
