



PRAHEALTHSCIENCES

The Highs, Lows and Lessons of a First-Time Study Lead

DATE

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PRESENTED BY

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Content of Presentation

- Who am I?
- Purpose of presentation
- Key areas of leading
 - Technical Tasks
 - Study Planning
 - Communication
 - Rewards!
- Questions



Who am I?

- Programmer at PRA Health Sciences since 2011
- Joined through the graduate training scheme.
- Experience as a team member in studies of various phases and indications.
- Leading studies for nearly two years.



Purpose of Presentation

- Encourage and share with other new leads
- Passing on lessons to future leads
- Reflection on the lead role



Key Areas

Technical Tasks



Study Documentation





Example – Annotating the CRF

Vital Signs for Safety

VS=Vital Signs

Which SDTM domain does this fit into?

1. Date dd-mm-yyyy

2. Actual Time (24-hour clock) - Hour List: HOUR

3. Actual Time (24-hour clock) - Minute List: MINSEC

4. Position VSORRESU VSPOS List: VSPOS

5. Systolic Blood Pressure (mmHg) VSORRES where VSTESTCD=SYSBP

6. Diastolic Blood Pressure (mmHg) VSORRES where VSTESTCD=DIABP

7. Pulse Rate (bpm) VSORRES where VSTESTCD=PULSE

8. Respiratory Rate (breaths per min) VSORRES where VSTESTCD=RESP

9. Temperature (Celsius) VSORRES where VSTESTCD=TEMP

10. Temperature Route VSLOC List: TEMPLOC

List: HOUR		List: MINSEC		List: VSPOS	
Label	Value	Label	Value	Label	Value
[Blank]		[Blank]		Sitting	SITTING
00	00	00	00		
01	01	01	01		

Which SDTM variables will the fields map to?

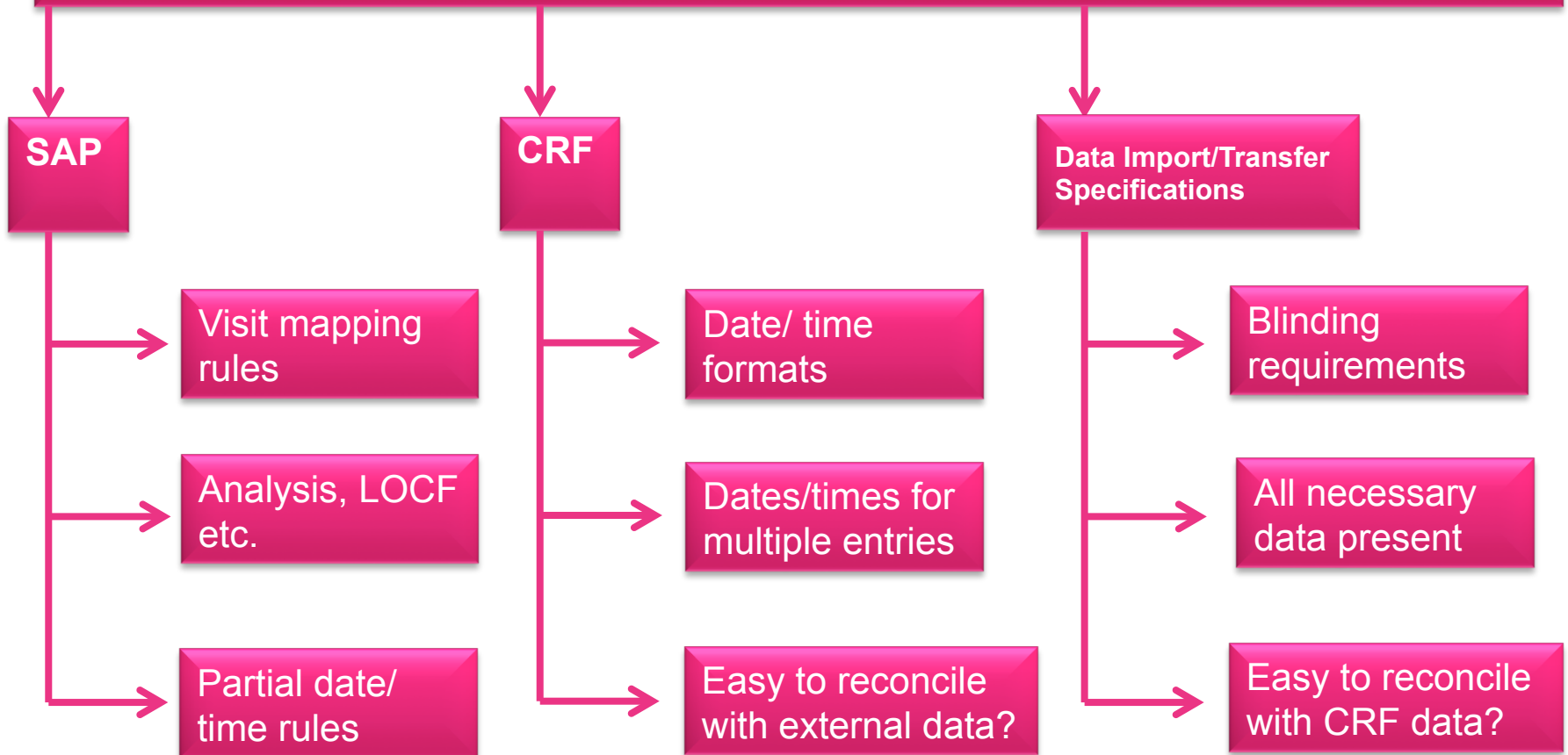
Will the fields be transformed into rows or columns?

Are there fields for all SDTM required and expected variables?



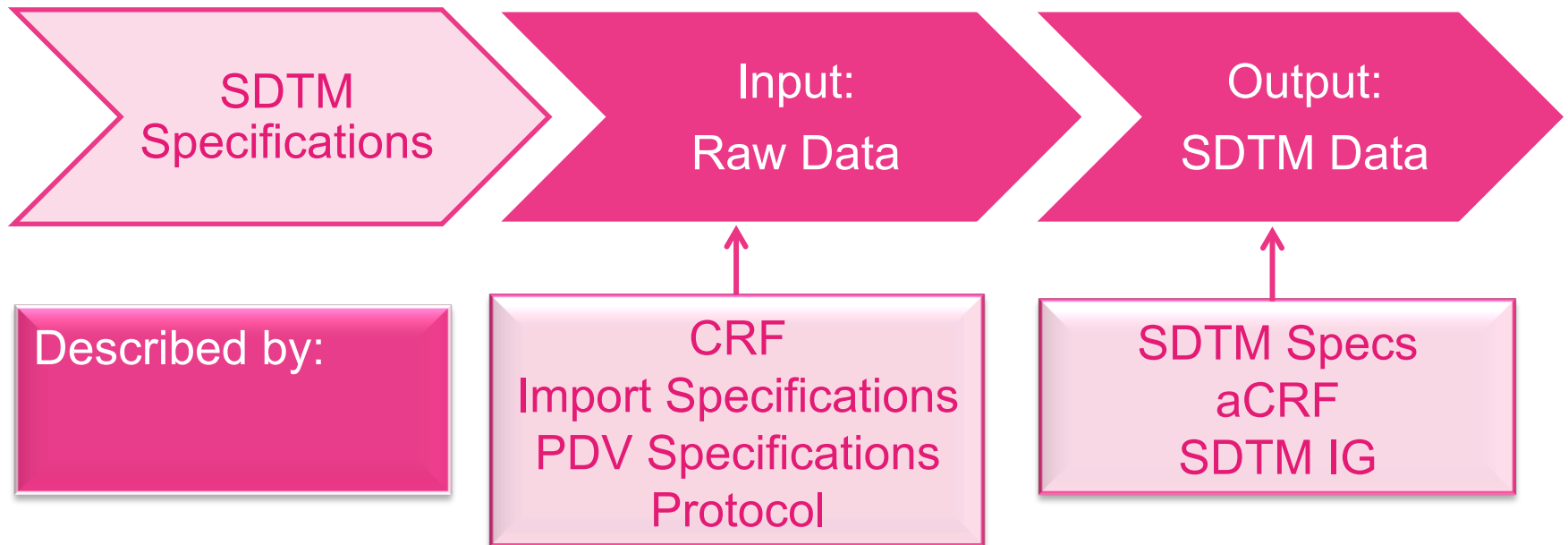
Document Review

Does this document contain all the information required to support programming?



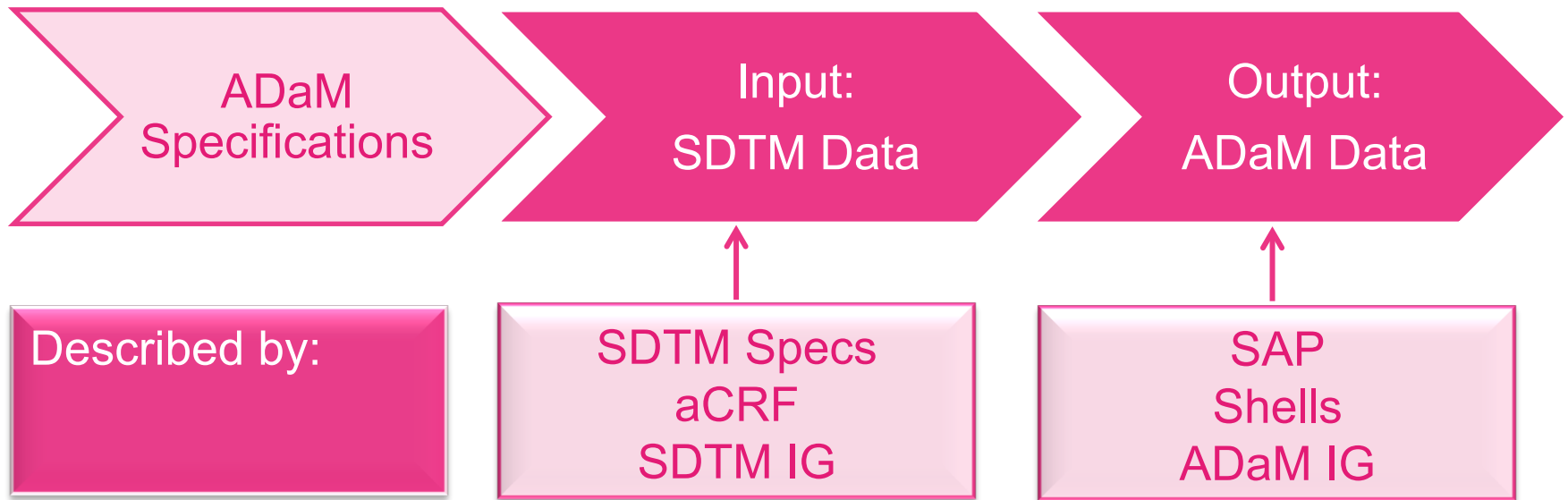


Specification Writing - SDTM





Specification Writing - ADaM





Programming Datasets

- Lead's involvement will vary depending on team/time.
- Worthwhile being involved in most complex and key domains.
- Work closely with your Statistician
- Iron out decisions/definitions early.



Technical Task Outline

- Have an active approach as a team member
- Ask questions
- Work closely with other colleagues
- Various tasks but the principle is consistent:

Ensure the documentation provides all of the required information to produce the relevant programming output and conforms to the applicable rules and standards related to such an item.



Key Areas

Study Planning

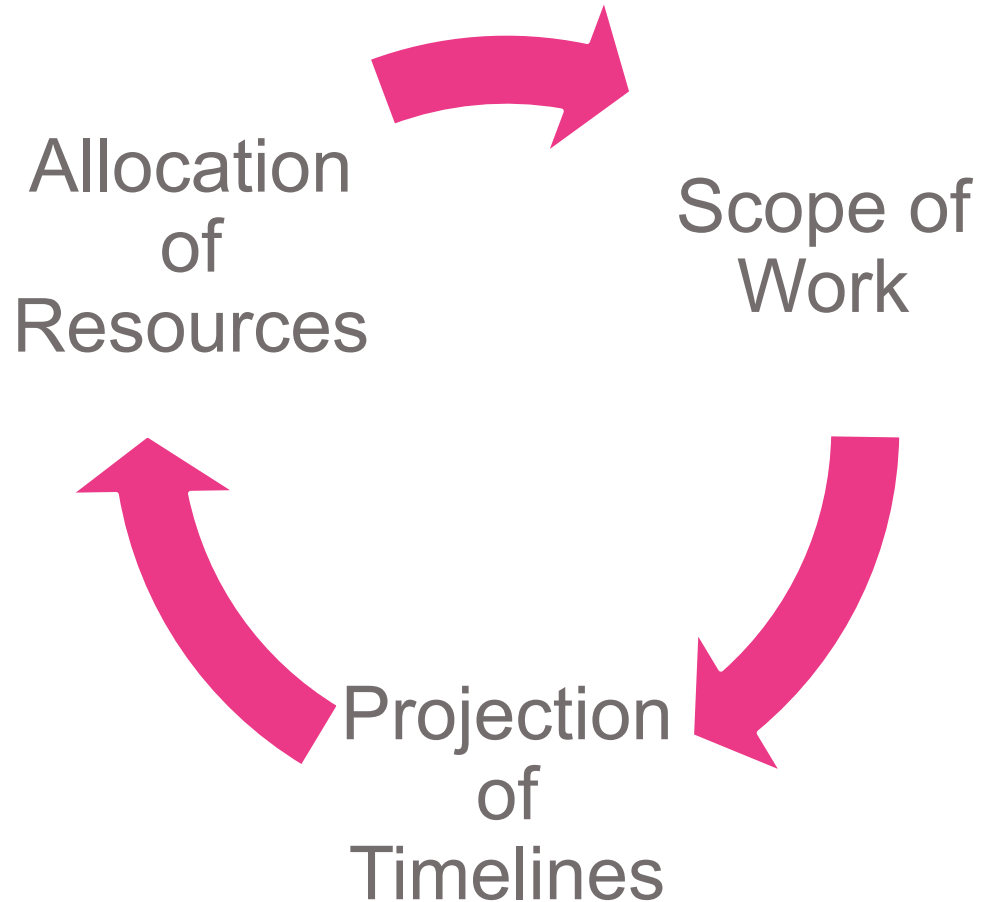


Introduction

- Can be challenging for new leads as very different skill to programming
- Easiest if monitored from offset
- Consider smaller, more manageable steps.
- Guidance provided here from CRO perspective – but mostly common principles.



Process





Project Scope

- Make a record of the planned numbers of units for each task.
- Make a record of the allocated numbers of hours per unit allowed for each task.
- Calculate total hours required, e.g.

25* SDTM
datasets



10* hours/
dataset



250* programming
hours

*Numbers for example purposes only



Out of Scope

- Keep a tracker of all additional tasks
- Calculate additional hours required, e.g.

1* unique table
4* repeat tables
1* listing



5* hours/unique
3* hours/repeat
1* hour/listing



5 + 12 + 1 = 18
programming hours

- Notify Project Management/Project Finance colleagues so that additional effort can be recognised or recovered.

*Numbers for example purposes only

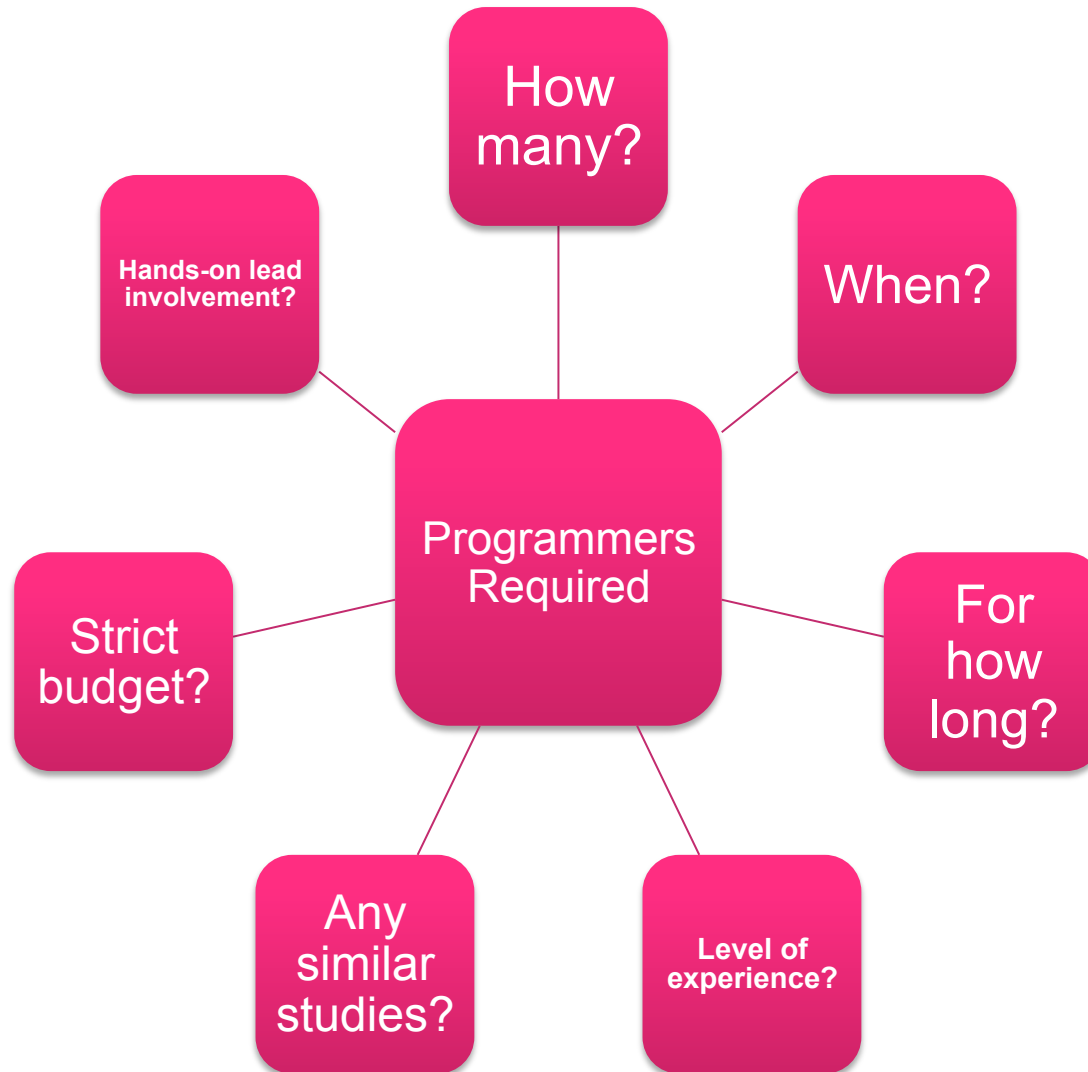


Projection of Timelines

- Gather all information first.
- Make use of available tools, SOPs/Work Instructions, example timelines and knowledgeable colleagues!
- Check the contract for –
 - How many data transfers (both from vendors, to client)? When?
 - FPFV (First patient first visit) date.
 - Number of Dry Run deliveries
 - Is there an Interim Analysis?
 - Is there a DMC? How many expected deliveries?
- Forward projection/backward projection.
- Have as much input into cross-functional discussions as possible.
- Consider a detailed breakdown to ensure enough time is allowed.
- It is better to project a longer timeline (within reason) that is likely to be met, than to project an earlier deliverable date which could potentially be missed.



Planning Resources





Thoughts about study planning

- As a new lead, study planning may well be one of your greatest challenges
- Take time and start early, you will be grateful later!
- Be prepared to learn lessons.
- Make the most of your functional manager – this is their area of expertise.
- Do not be afraid to ask questions.

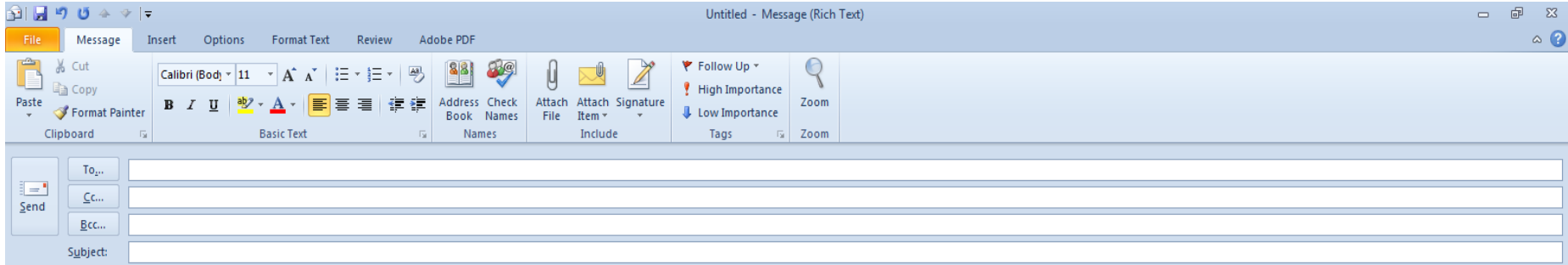


Key Areas

Communication



Email – Pros, Cons, Hints & Tips



- Probably most common method of communication as they are quick and versatile
- Also easily misinterpreted or lost – be clear, courteous and conscientious
- Helpful in-built functionality
 - multiple participants, attachments, integrate with calendar, alerts, categories, easily archived, rules to automate these actions.
- Volume of emails will definitely increase as you begin leading. Certainly worth keeping them organised and responding promptly.
- When composing emails, ensure you assign a clear and concise subject
- Maintain a relevant subject field – often email threads become very long and topic changes over time, it may be sensible to update the subject field for your reference later.



Alternative Means of Communication

Phone calls

**Centrally
stored
documents**

**Team
Meetings**

Face to face



Cross-functional communication

- Communicate early
- Ask questions
- Respond within a reasonable timeframe
- Use phone/face-to-face if possible
- Use appropriate language



Global Challenges

- Many companies have bases across continents
- Consider time zone, culture and language
- If communicating in English, allow those who are not first-language to determine their preferred style
- Share dates of public holidays
- Appreciate each other's working environment and leadership structure.



Key Areas

Rewards



Your first study may not be perfect but...



The Big Picture



Key Areas

Final Thoughts



| Any questions?





PRAHEALTHSCIENCES

THE FUTURE OF CLINICAL DEVELOPMENT