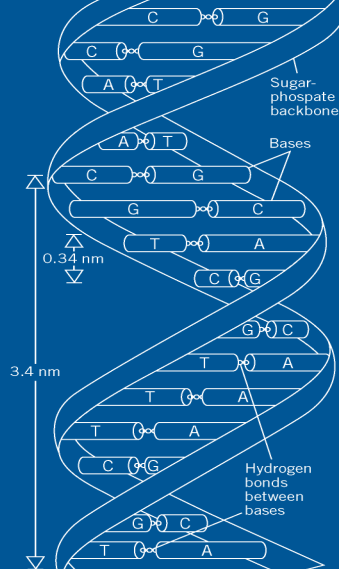




Challenges of Clinical Projects shared between Pharma Companies

Olivier Leconte

Roche Basel

18th October 2010

Let's have you work first

1. What is the cost to develop a new drug ?

\$750m

\$1b

\$1.5b

\$2b

Answer : **\$1.5b**

2. Raise your hand if you or your team(s) are working on a drug not coming from your own company research ?

Presentation Objectives

- Why do Pharma companies share drug development ?
- Present a collaboration between 2 Pharma companies from 2006 to 2010
- Share ideas on how you could run such collaboration
- **Revise your “Music” Culture of the last 4 years**



Today's Drug Development Landscape

- 
- More and more pharmas are working with small research units/organizations, biotech or large pharma to develop/promote new drugs.
 - Benefits : sharing cost, acquire new technology or supplement their own early dev pipeline
 - Different scenarios :
 - ✓ Small unit discovers, big pharma gets approval
 - ✓ Target « local » markets
 - ✓ Inherited from previous merger

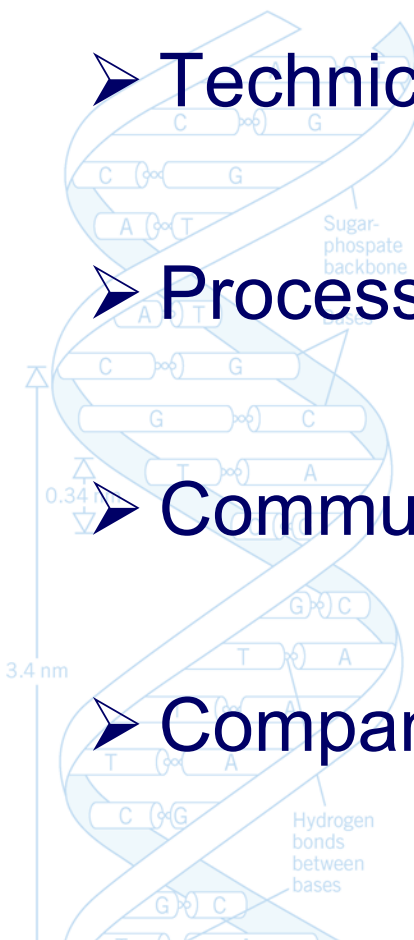
Challenges in such collaboration

➤ Technical

➤ Process

➤ Communication

➤ Company culture



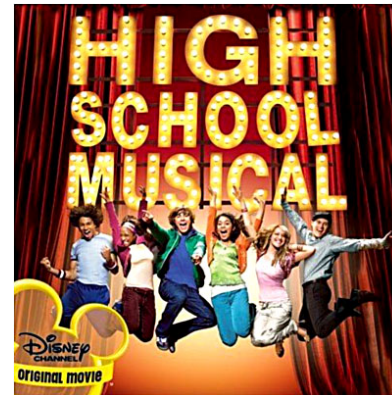
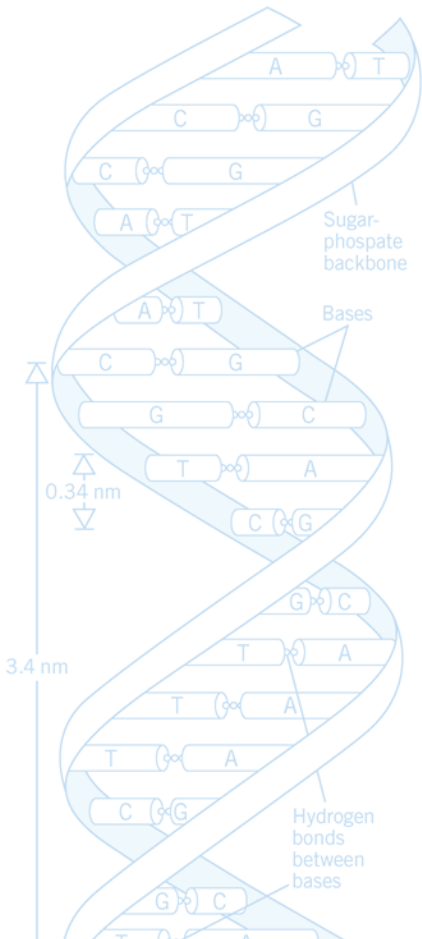
Once upon a time, in a galaxy not that far away.....



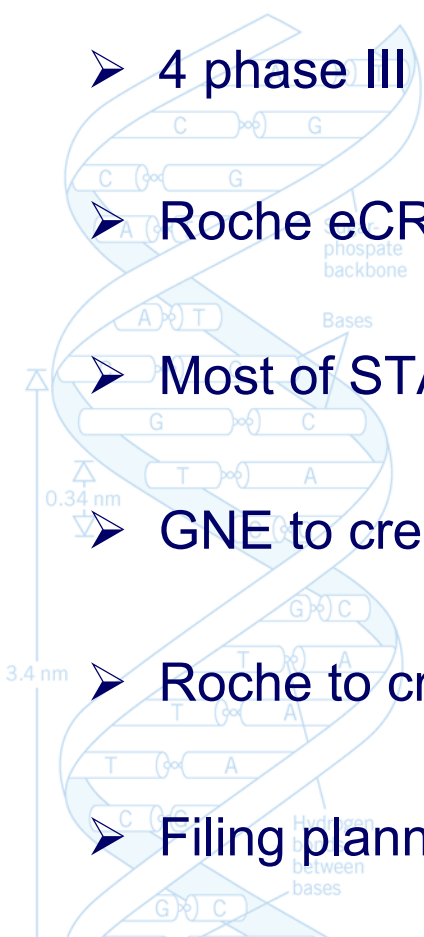
- Roche, Genentech and BiogenIDEC developed and filed Mabthera first generation of anti-CD20 Rheumatoid Arthritis drug
- Roche and Genentech agreed to develop a chimeric version of this drug
- Genentech responsible for US market, Roche responsible for ROW
- Both companies ran « local » Phase II studies

And our story begins in....

2006



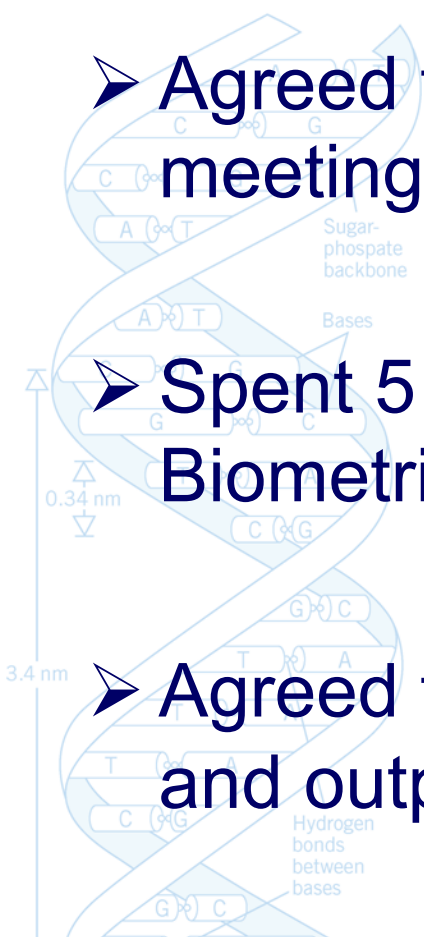
2006....

- 
- 4 phase III studies to be launched by end of 2006
 - Roche eCRF to be used
 - Most of STAT and Programming activities to be done by Roche
 - GNE to create FDA package
 - Roche to create EMEA + ROW package
 - Filing planned 2Q10

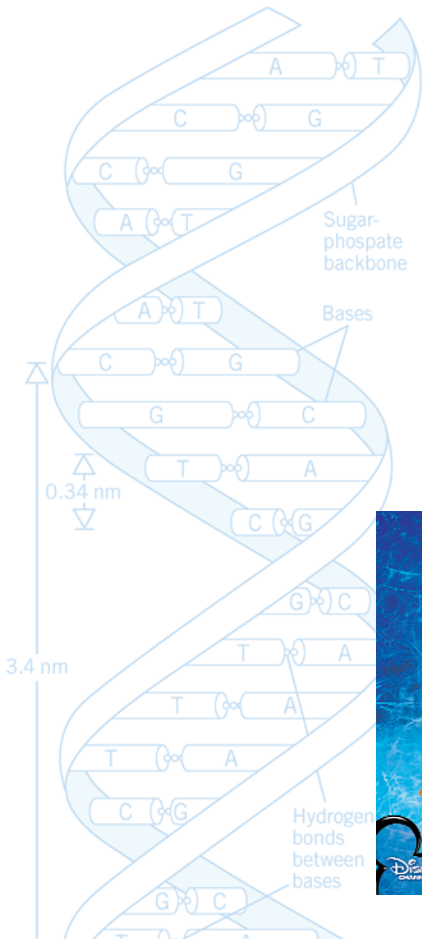
2006 Challenges

- 
- Get to know each other
 - How to ensure that GNE will be able to prepare for FDA and answer FDA questions if «everything» is done by Roche ?
 - 8h time difference
 - Duplicates in many areas. How to ensure smooth and efficient communication ?

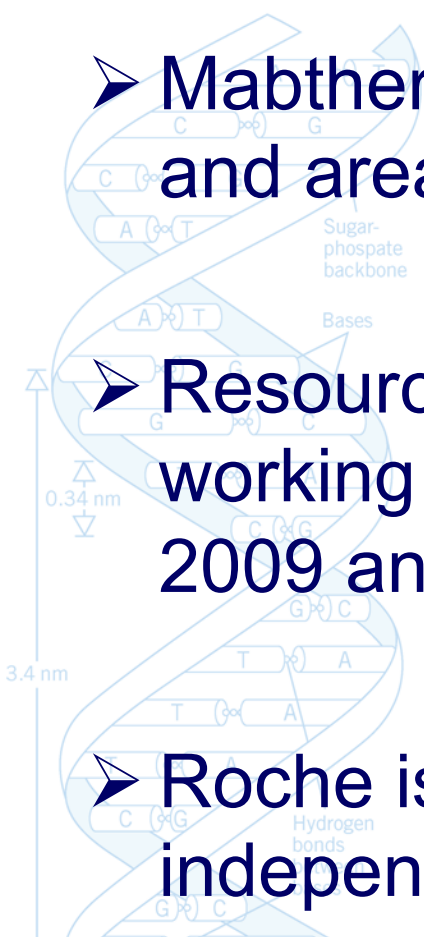
2006 Decisions

- 
- Agreed to have a F2F at least once a year. First meeting in November 2006
 - Spent 5 days going through each company's Biometrics processes
 - Agreed that GNE will QC main analysis datasets and outputs on Roche computing environment

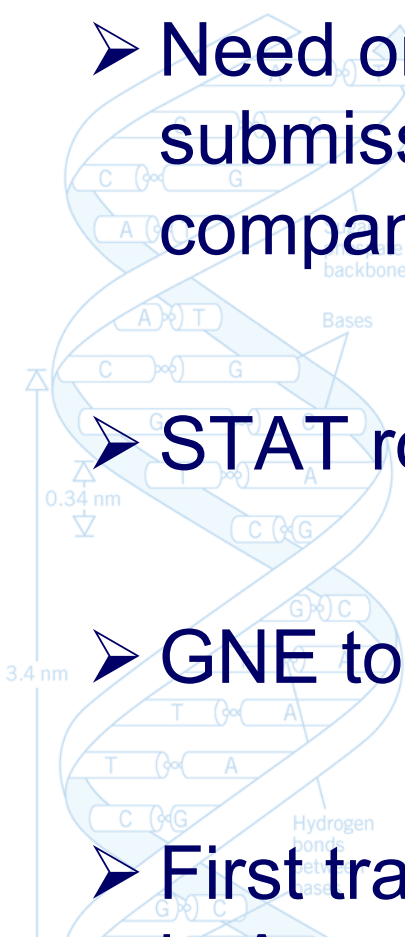
2007



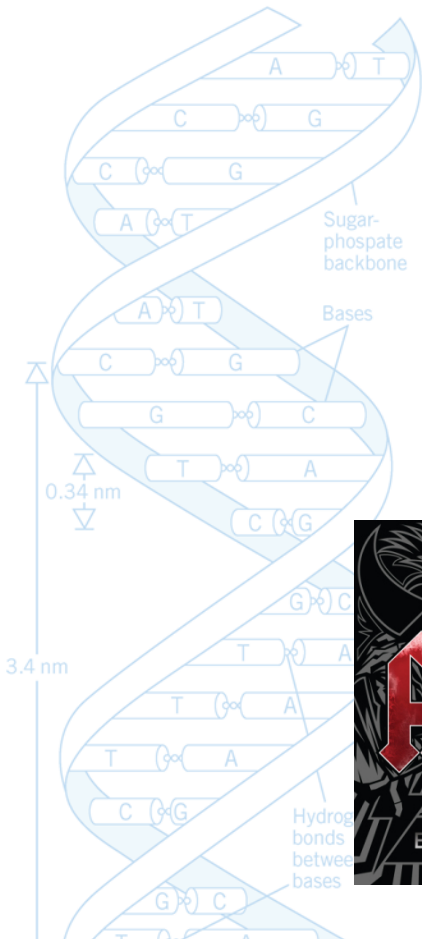
2007 Challenges

- 
- Mabthera 2nd filing → learning from its success and areas of improvements
 - Resources are tight within Roche as we are working on 3 RA compounds with filing in 2008, 2009 and 2010
 - Roche is starting to work with India for independent QC

2007 Decisions

- 
- Need one data standard facilitating FDA submission and communication between 2 companies : SDTM & ADAM
 - STAT roles & responsibilities are evolving
 - GNE to take on some first line activities
 - First training to Roche Computing Environment in August 2007 in San Francisco

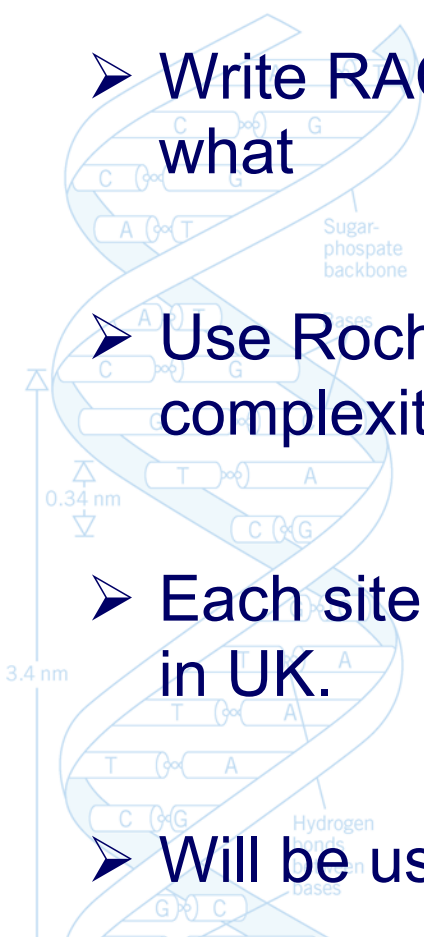
2008



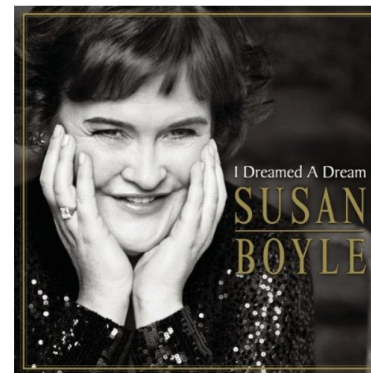
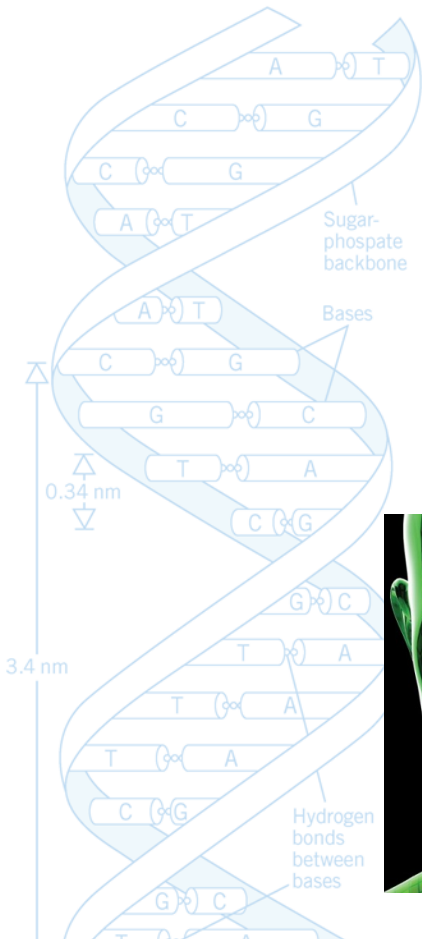
2008 Challenges

- 
- We have to start
 - Team is expanding but needed resources will come later than expected
 - All DBLs are coming together in 6/8 weeks time frame starting Christmas 2009
 - Roche Operational Center India is up and running

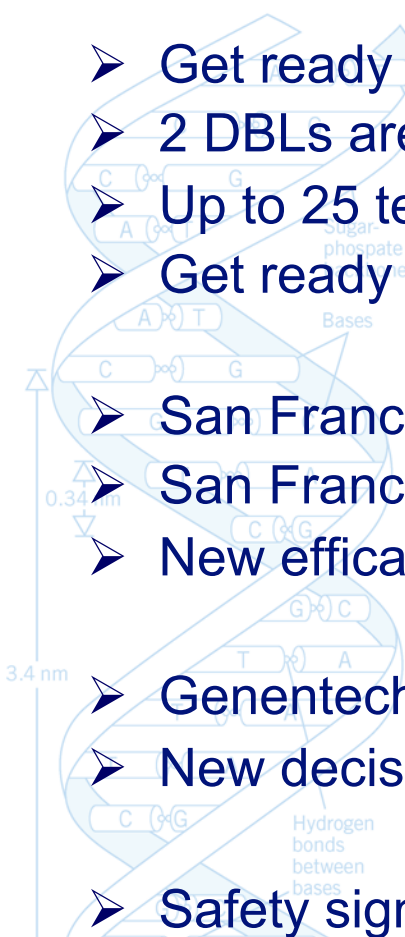
2008 Decisions

- 
- A faint background illustration of a DNA double helix. It shows the sugar-phosphate backbone as two intertwined strands, with nitrogenous bases (A, T, C, G) connected by hydrogen bonds. Labels include 'Sugar-phosphate backbone' and 'Hydrogen bonds'. Dimensions are given as 0.34 nm for the width of the helix and 3.4 nm for the length of one full turn.
- Write RACI matrix to agree on who is responsible for what
 - Use Roche Mumbai and QC GNE groups depending complexity of QC activities
 - Each site will take lead on 2 studies. Safety will be done in UK.
 - Will be using first study to develop project level programs

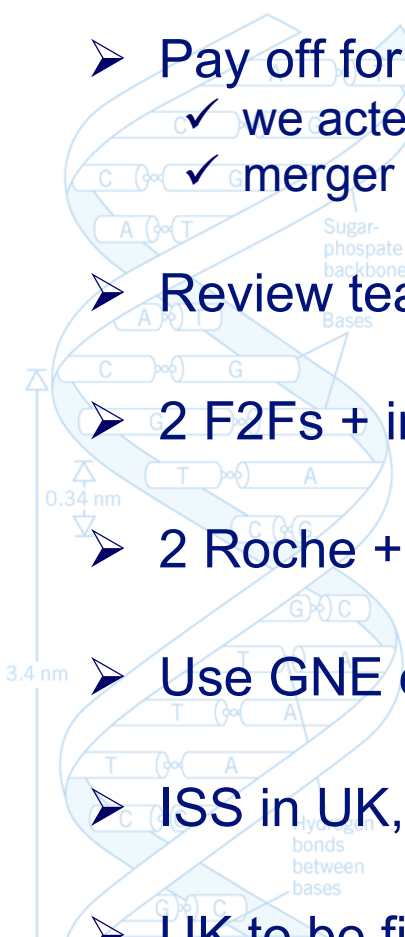
2009



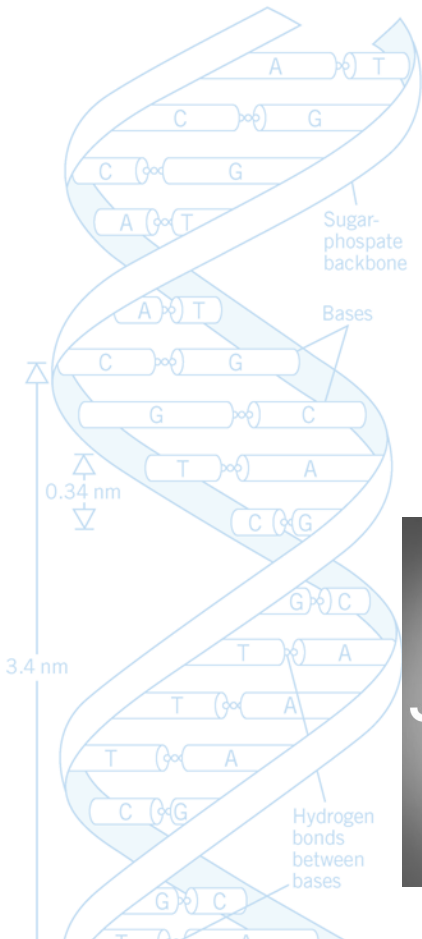
2009 Challenges

- 
- Get ready for 1st DBL mid December
 - 2 DBLs are 2 weeks apart, 3rd coming end of January
 - Up to 25 team members across 4 sites
 - Get ready for e-Sub
 - San Francisco to work on Roche Computing Env.
 - San Francisco to work with India
 - New efficacy reporting tool to be used
 - Genentech acquisition announced and completed
 - New decision process to be implemented following integration
 - Safety signals identified in Asia-Pacific region

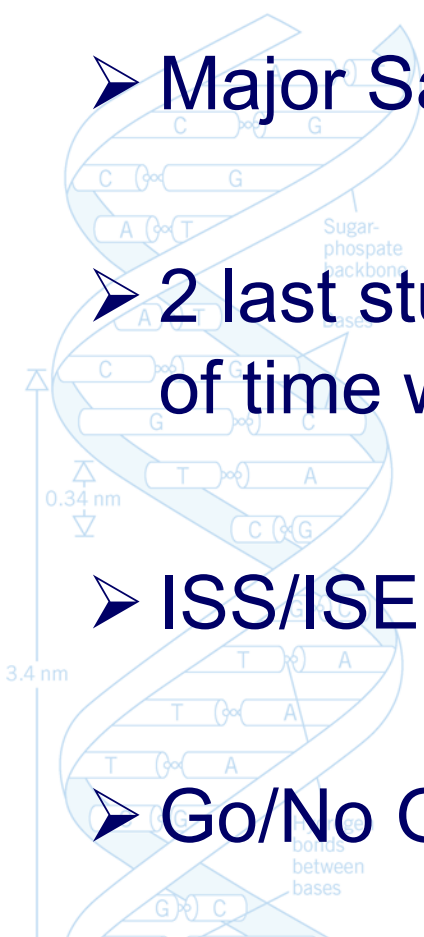
2009 Decisions

- 
- Pay off for previous decisions :
 - ✓ we acted as one team
 - ✓ merger talks/decisions/concern did not really affect us
 - Review team members assignment when needed
 - 2 F2Fs + individual trips + webex
 - 2 Roche + 1 GNE travelling to Mumbai
 - Use GNE e-sub process
 - ISS in UK, ISE in US
 - UK to be final decision maker

2010



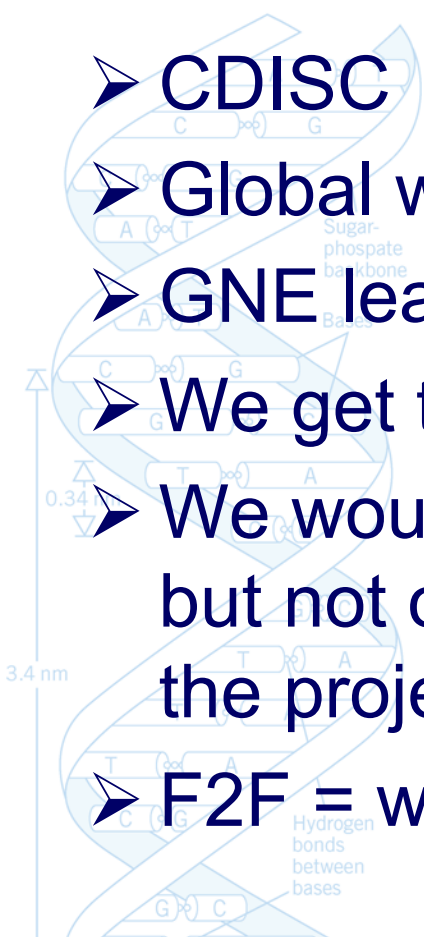
2010 Challenges

- 
- Major Safety issue identified by DSMB
 - 2 last studies to be reported over a short period of time with safety concern
 - ISS/ISE to be put on hold
 - Go/No Go by April 2010

2010 Decision

- 
- All activities to be repatriated in the UK
 - “No Go” decision made in March 2010
 - By May 2010, 80% of resources re-assigned

What have we learned ?

- 
- CDISC
 - Global working
 - GNE learned Roche computing environment
 - We get to know “future” colleagues
 - We would have used less resource on one site...
but not one site had enough resource to support the project entirely.
 - F2F = weeks of TCs

Take away message

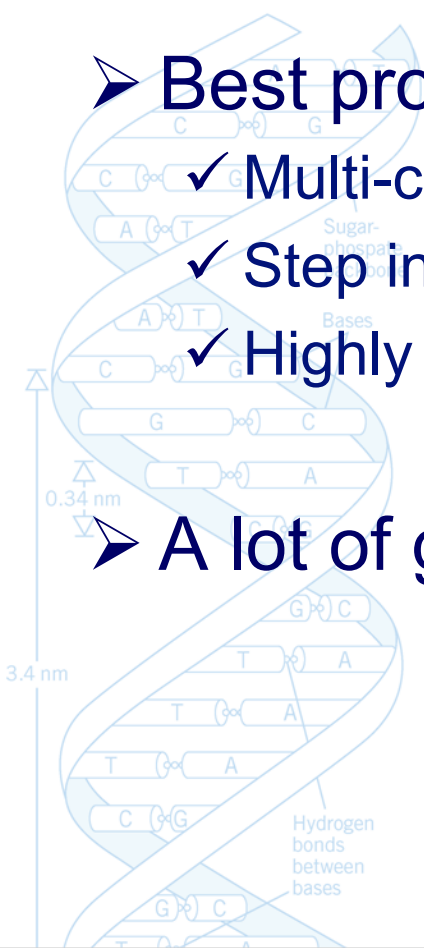
➤ Communication, Communication, Communication

➤ “One team” spirit

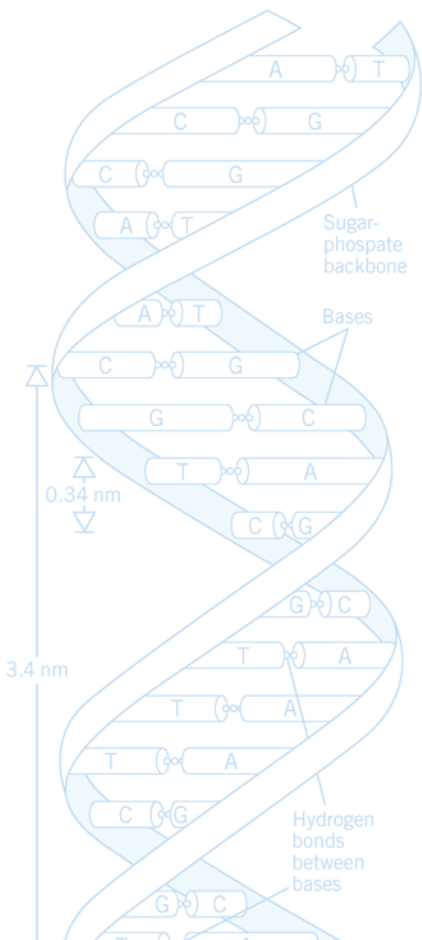
➤ When possible use one system/set of processes/
data standards



My feelings

- 
- Best professional experience
 - ✓ Multi-cultural
 - ✓ Step in someone else shoes
 - ✓ Highly efficient and dedicated team
 - A lot of great memories and fun





THANK YOU