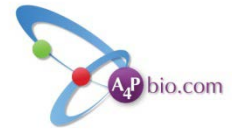


# Bio-logistical Considerations in Planning and Executing Early Phase Bioanalytical Studies

*EBF – Barcelona - Friday 22<sup>nd</sup> November 2013*

Scott Vincent BSc (Hons), M.I.L.T

# Who am I?



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## **Current**

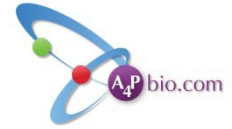
- *Two years as logistics director for A4Pbio*
- *Providing bio-logistic solutions for pre-clinical / clinical trials & distribution of stem cell & bio-therapeutics*
- *Consultancy, project management & scheduling*

## **Previously**

- *For ten years coordinated all sample shipping for Pfizer's Global early development portfolio*
- *Supported PK, PG & BM shipments*
- *Extensive experience with time & stability sensitive samples*
- *10K+ consignments*

- **Bioanalysis & Logistics Linked**
- **Can be similar in perception**
- **Dreamlifter**

# Sample Logistics...



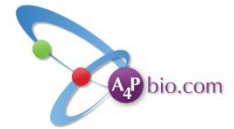
Clinician X “well I get on a plane at LHR and I’m in NYC by lunchtime”

BUT its not as simple for a sample shipment...!

***Sample/s drawn, labelled, spun, plasma separated, transfer tubes, labelled, cross checked, frozen, documented and cross checked into a bag, carefully deep frozen, packed compliantly, box labelled, final documentation produced, sent to collection point, handed to a courier, paperwork checked, driven to the airport, delayed on the M20, delayed on the M25, handed to the airline, sorted, weighed, screened, compete with overweight luggage, compete with live animals, flight, offloaded, slightly damaged, transfer airline shed, customs cleared, sorted, handed to courier, returned to office, dry ice & box checked, Customer SOP checked, re-packed, delivery courier assigned, driven to destination, delayed Van Wyck Expressway, delayed in the Queens midtown tunnel, signed for, screened, sorted, delivered to lab, passed to consignee, box condition & dry ice level checked, unpacked, accessioned, stored / processed, chain of custody documentation returned...ANALYSED***

# Planning Robustly & Effectively...

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**Early Involvement** – Consider logistics in planning studies and selecting sites

**Professional input** – Alternatives & new ideas / modes / consider the consequences e.g. customs value

**Managing expectations** – What is possible & the risks

**The real world** – Geopolitical climate, national holidays, large events

**Seasonality** – Long studies... factor in the seasonal effect, peak travel, extreme cold & summer Vs. winter scheduling

**Strategic Vendor Selection** - Using the right vendor for the scenario

*The right approach, strategic fit & experience*

**Back-up options** - Realism & impact

**Flexibility** – Ability to change the plan “because it invariably does”

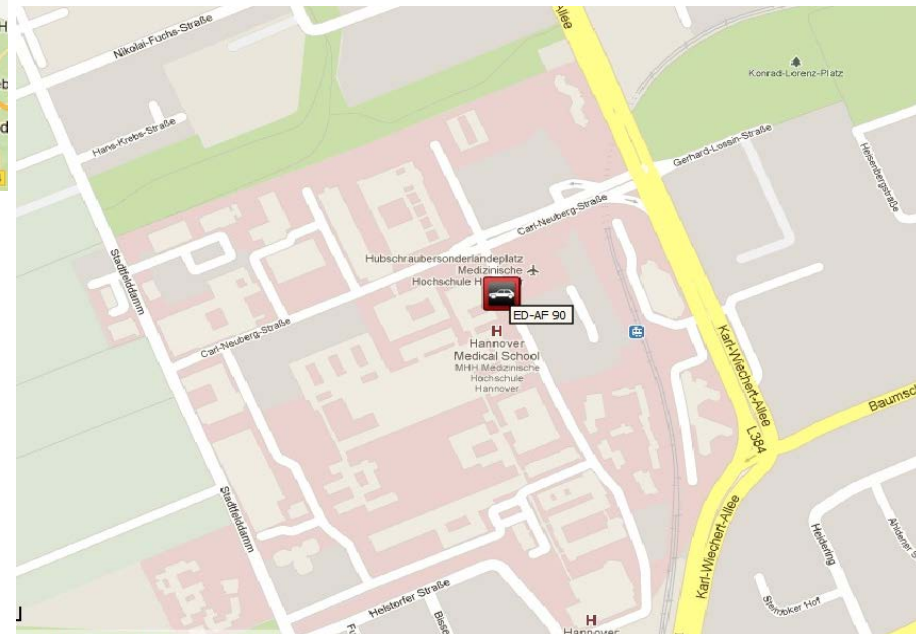
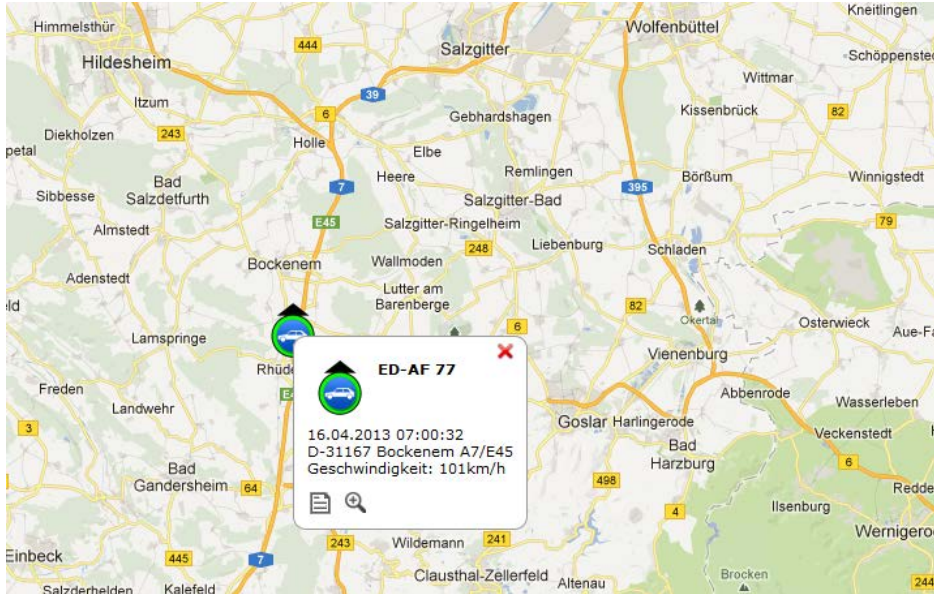
## How do we ship fast?

- NFO
- Direct drive
- Dedicated aircraft
- Out of hours

## How do we get it right?

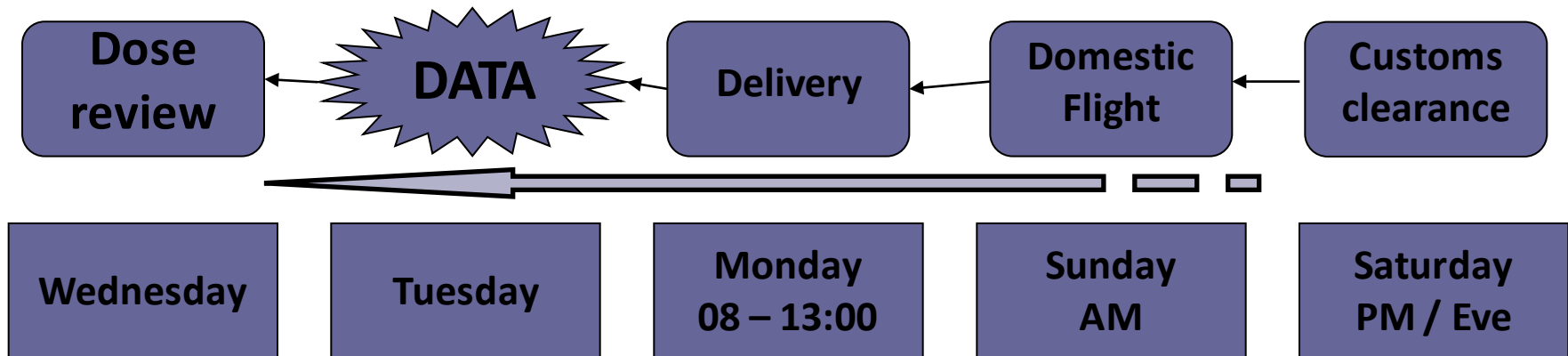
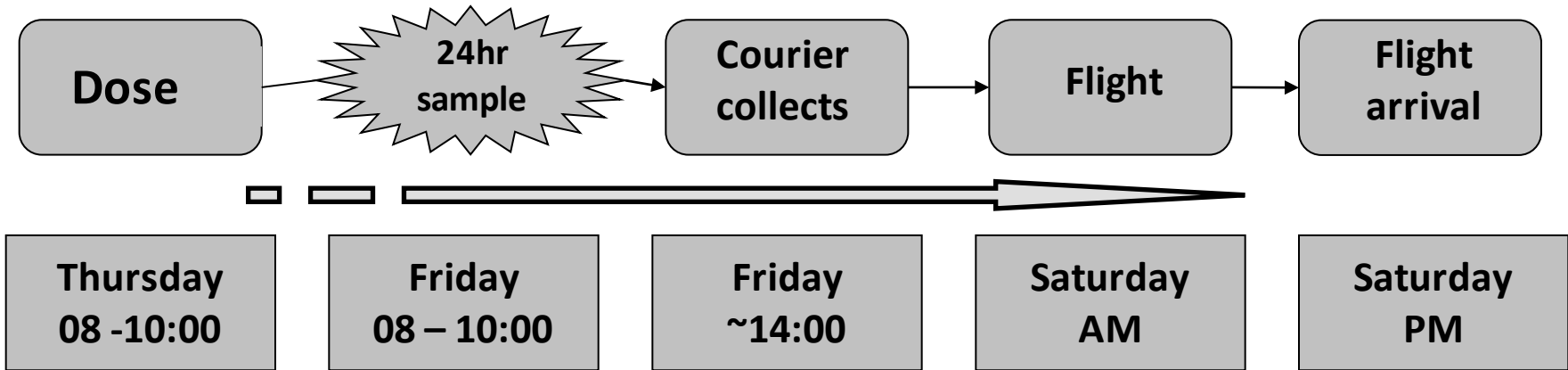
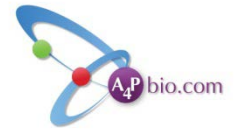
- Define critical / understand why
- Roles understood / communicated
- Try and keep it simple
- Understand critical control points
- Back-ups

# Fast paced Logistics...Buying the analyst time

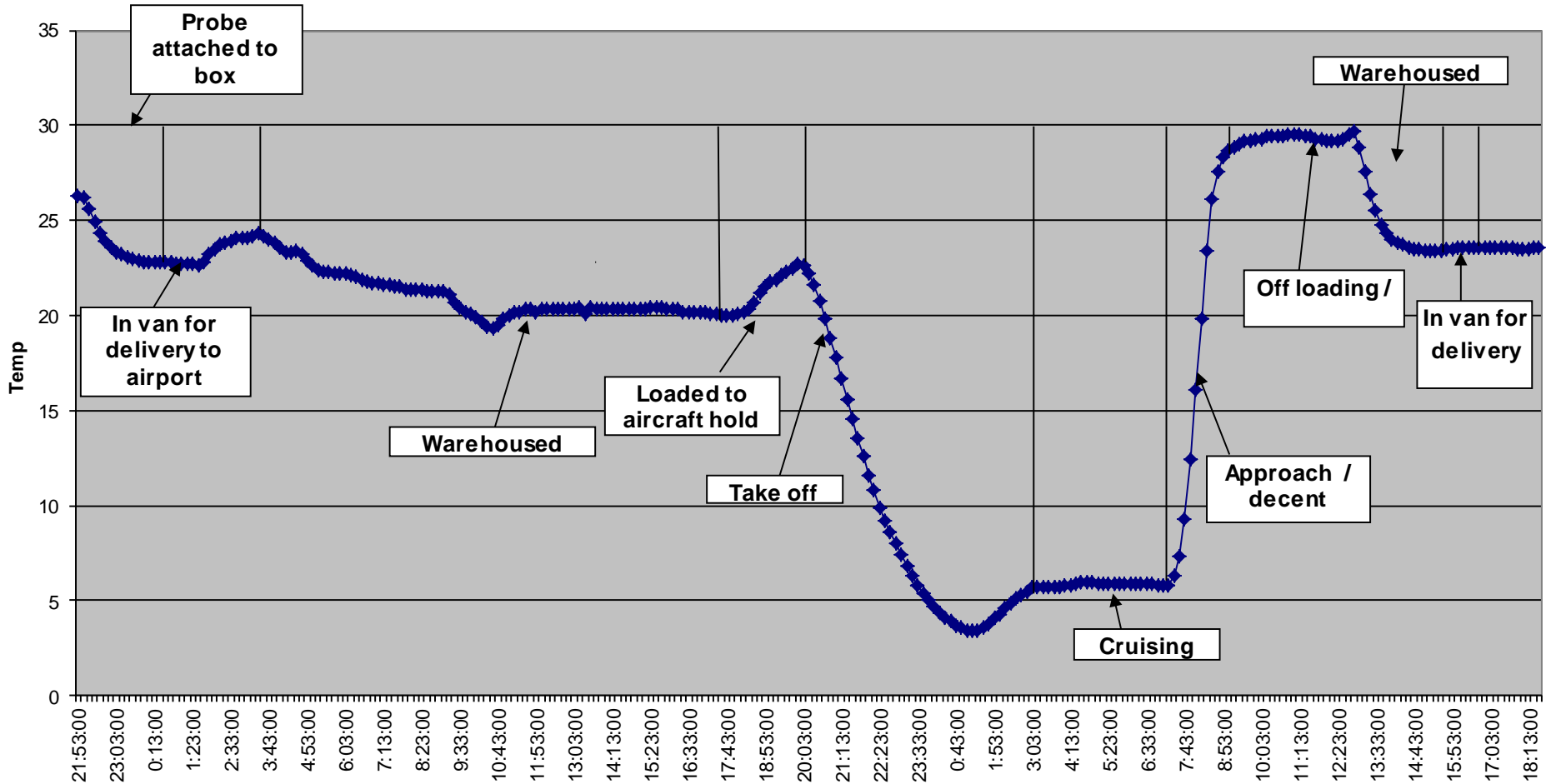




# Fast paced Logistics...Buying the analyst time



# Stability in transport & Chain of custody...



- **The FIRST MILE**

- Everything included?
- Packed correctly?
- Pick-up time
- Set out your likelihood of success

- **The LAST MILE**

- Waiting Resources
- Packaging is tested
- What happens POST POD?

- ***Compliance***

- *Document it (Inventory, tracking forms)*

- *Data feedback*

- *Oversight*

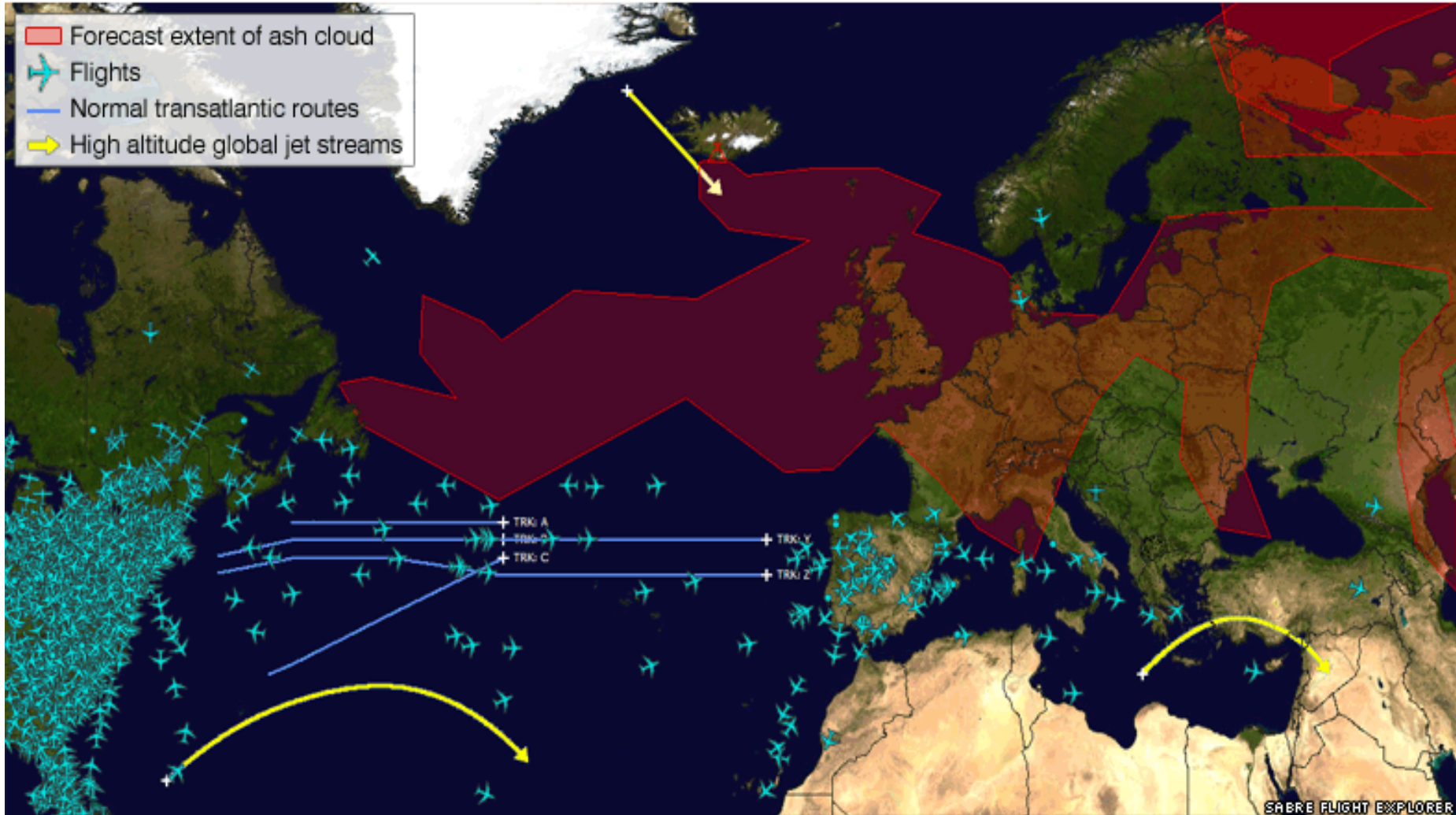
# The Unforeseen: Eyjafjallajökull Volcano 2010...



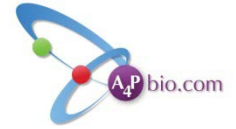


# Eyjafjallajoekull Volcano 2010...

Snapshot of North American and European flights 19 April, 1300 GMT



## Other Examples of the Unforeseen...



***Weather/Nature*** - Fog, snow, ice, storm

***Air*** – Not loaded / unloaded, driver / pilot illness, breakdowns, ATC & customs strikes

***Animal*** – Incompatible cargo

***Rail*** – Not unloaded “in south of France”

***Road*** – Heavy traffic, RTA, Bank robbery in Paris!

***Sea*** – French fisherman blockade Calais port

***Under-sea*** – Euro star train iced up

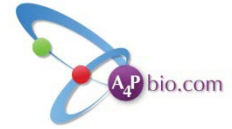
***Threat of terrorism*** – London lockdown

***EU Border police*** – Hungarian police

***Bizarre*** – Shipper rushed into hospital minutes before collection / Flight could not land as the runway is being re-surfaced!



# When Disaster Hits... How to Hit Back?



- **Secure the samples & mitigate risk**
  - Assess send / no send decision
  - Don't send them... temporary & unsustainable
  - Locate & secure your consignment
  - Maintain temperature of samples
  - Know your courier's limits
- **Communicate**
  - Maintain the information flow,
  - Never assume stakeholders know
- **Be creative with routes**
  - Utilise other modes... domestic truck, exclusive vehicle, rail

# Take Home Messages...



- Consider logistics in your initial plans
- Plan and prepare
- Partner & understand your courier
- Communicate – right info to right people
- Utilise technology
- Consider your back-up as if it were **PRIMARY**

## Thank You for Your Attention & Questions...

### **A4Pbio**

Innovation House  
Discovery Park  
Ramsgate Road  
Sandwich  
CT13 9ND  
United Kingdom

**Web:** [www.a4pbio.com](http://www.a4pbio.com)

**Tel:** +44 (0) 1304 249107

**E-mail:** [info@a4pbio.com](mailto:info@a4pbio.com)

