Discover how SGS’s clinical pharmacology unit team has brought scientific and operational concrete and innovative solutions to its clients’ early phase drug development trials.

1. Development Inhaled Drugs Floor Approach
2. Execution Bone Marrow Puncture
3. Patient Population – Complex Imaging
4. Sample Handling And Shipments
5. Study Specific Recruitment Plan
6. Organisation At Non-CPU Location
7. Design And Trial Set-up
8. Fast Implementation During Adaptive Design

**DEVELOPMENT INHALED DRUGS FLOOR APPROACH**

- **SPONSOR**  
  Large Pharma
- **STUDY**  
  Phase I/ open label / healthy volunteers
- **COMPOUND**  
  Drug for obstructive airway disease
- **CHALLENGES**
  - Inhaled drug / potential cross contamination
  - Charcoal block / randomisation
  - Strict inhalation process (8 puffs in 3mn 20s)
  - Tight sampling time points with critical blood collection at 5 minutes post dose
- **APPROACH**
  - 2 separated dosing rooms / 2 dosing teams / dedicated floor
  - “Traffic light“ control of HV flow / dedicated staff / roadmap explanation to HV
  - In-depth training staff / clear explanation to volunteers
- **CONCLUSION**
  - Successful execution – no PK out of window
  - Containment of cross contamination by using dedicated sub-unit
  - Timely planning / dedicated teams / roles
**EXECUTION BONE MARROW PUNCTURE**

- **SPONSOR**: Large Pharma
- **STUDY**: Phase 0/ healthy volunteers
- **CHALLENGE**: Bone marrow puncture
- **APPROACH**
  - Collaboration with haematologist
  - Top laboratory analyst of sponsor trained CPU staff, and performed the sampling together with CPU staff
  - 20 punctures on 1 Saturday afternoon
- **CONCLUSION**
  - Successful complex PD sampling
  - Close collaboration with sponsor analyst
  - Close collaboration with specialist, for PD execution

**PATIENT POPULATION – COMPLEX IMAGING**

- **SPONSOR**: Mid Size Pharma
- **STUDY**: Phase I / IIA - Healthy subjects / patients with brain lesions
- **CHALLENGES**
  - Intravenous injection
  - Magnetic Resonance Imaging (MRI) during trial
  - Healthy Volunteers + brain lesion patients
- **APPROACH**
  - Collaboration specialists for patient referral
  - Mobile MRI rented and operated on per patient basis
- **CONCLUSION**
  - Efficient specialist referral for specific patient population
  - Successful imaging organisation (MRI) per patient

**SAMPLE HANDLING AND SHIPMENTS**

- **SPONSOR**: Large Pharma
- **STUDY**: Phase I / FIM, SAD, HV
- **COMPOUND**: Receptor inhibitor
- **CHALLENGE**
  - Complex sample handling on multiple time points in 8 staggered dosed groups of 8 subjects
  - Regular fixed shipments
- **APPROACH**
  - 2-day training on sample handling for CPU staff at sponsor laboratory
  - Close teamwork to ensure complex shipment schedule
- **CONCLUSION**
  - Clear scheduling for dosing interval / length, tight blood draw schedule
  - Avoiding cross contamination through planning at right sub-unit
  - Optimised operational execution (traffic control) with Timely planning / staff training
## STUDY SPECIFIC RECRUITMENT PLAN

<table>
<thead>
<tr>
<th>SPONSOR</th>
<th>Mid Size Biotech</th>
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<tbody>
<tr>
<td>STUDY</td>
<td>Phase I/ PK/PD Safety</td>
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<tr>
<td>COMPOUND</td>
<td>Antibody</td>
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<td>CHALLENGE</td>
<td></td>
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<tr>
<td></td>
<td>Recruitment of 40 women NCBP 18-64y out of 433 women in the database</td>
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<tr>
<td>APPROACH</td>
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<tr>
<td></td>
<td>Dedicated recruitment officer</td>
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<td>Extensive advertising campaign including call center, posters, blog, banners and social media (facebook)</td>
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<td>Flexible screening approach</td>
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<td>CONCLUSION</td>
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<tr>
<td></td>
<td>Flexibility recruitment &amp; screening activities</td>
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<td>Trial specific recruitment plan implemented</td>
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## ORGANISATION AT NON-CPU LOCATION

<table>
<thead>
<tr>
<th>SPONSOR</th>
<th>Large Pharma</th>
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<tbody>
<tr>
<td>STUDY</td>
<td>Phase I/ Safety</td>
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<tr>
<td>COMPOUND</td>
<td>Sedatives/Hypnotics</td>
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<tr>
<td>CHALLENGE</td>
<td></td>
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<td></td>
<td>Elderly subjects to perform driving test the morning after evening dosing</td>
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<td>APPROACH</td>
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<tr>
<td></td>
<td>Subjects recruited at CPU, stayed at hotel in Tongeren</td>
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<td></td>
<td>Continuous supervision by PI, CRC, CTN at both locations</td>
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<td>Organisation of mobile lab, cognitive testing, tests / assessments in hotel</td>
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<td>Driving test on the road</td>
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<tr>
<td>CONCLUSION</td>
<td></td>
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<tr>
<td></td>
<td>Ad-hoc set-up of phase I unit in local hotel</td>
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<tr>
<td></td>
<td>Recruitment of elderly population</td>
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</table>
### DESIGN AND TRIAL SETUP

- **SPONSOR**: Mid Size Biotech
- **STUDY**: Phase I / DDI
- **COMPOUND**: Antiviral agents (NNRTI)
- **CHALLENGE**
  - Study design based on subject menstruation cycle (regulated / synchronised)
  - Randomisation to different treatments with different designs
- **APPROACH**
  - Start all subjects on same contraception at the same moment in their cycle
  - All subjects stop contraception on exact same day
  - Build design on estimated cycle time with proper windows
- **CONCLUSION**
  - Well designed organisation around subject menstruation cycles
  - Multiple variables well executed
  - Fast response to different situations and obstacles driven by human nature factor

### FAST IMPLEMENTATION DURING ADAPTIVE DESIGN

- **SPONSOR**: Mid Size Biotech
- **STUDY**: Phase 2a / PK safety / Tolerability
- **COMPOUND**: Vaccines
- **CHALLENGE**
  - Working with a virus in our Isolation (Human Challenge) Unit
  - Adapting design during the trial execution
- **APPROACH**
  - New WI created, trained and implemented during study start (eg. nasal swabs)
  - Clear communication (nurse / lab technician) for handling of biological samples
  - Fast reaction to design changes by sponsor and CPU teams (last minute)
- **CONCLUSION**
  - CPU staff was experienced to implement new procedures, approaches, materials in a minimal time frame
  - Efficient adaptation to design changes by floor staff

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