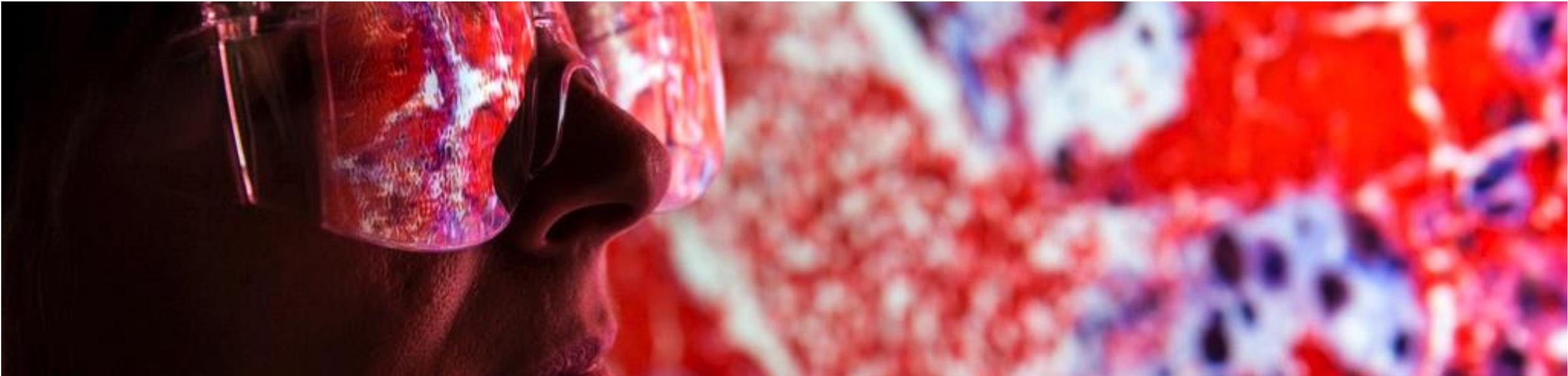


Patient-Centricity at AstraZeneca

Prepared for ICR Events Meeting

Sarah Durston, Country Head, Site Management & Monitoring UK, Clinical Operations, AstraZeneca 11th April 2019



Topics to Cover

1. Background to why AZ are adopting Patient Centricity opportunities across our programs
2. Methods AstraZeneca is using to Gather Patient Insights & Patient Engagement Tools
 - Case Studies
3. Patient Centricity is Business as Usual?



Reasons to include Patient Engagement

Clinical trials are conducted to improve patient health outcomes & quality of life

Clinical trials are becoming ever more complex with increasing recruitment & retention challenges

Trials designed solely to show clinically statistical endpoints may miss the very essence of understanding our patients and what will ultimately promote patient compliance and significantly improve outcomes in the real world setting

In the UK, the ethics submission (IRAS form) includes a section –

In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

The UK health departments are actively committed to supporting public involvement in all stages of research –

- March 22nd : [Health Research Authority](#) announced they are developing a set of **national expectations with regards patient involvement in research**



Patient Centricity & AZ

Guy Yeoman (VP Patient Centricity, Global Medical Affairs) published in BMJ an article to define what is meant by **Patient Centricity** – a definition meaningful to and validated by patients/carers:



Putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best possible experience and outcome for that person and their family

Published March 2017



AZ Patient Centricity

- AZ Patient Centricity Team was established early 2016
- Comprises 4 staff
 - 3 Patient Engagement Directors (one per TA)
 - 1 PaCe Partnership Director (support relationship with Patients Like Me and other vendors)
- Patient Engagement Lead (PEL) assigned to actively manage the patient engagement process – liaises with each study team
 - support global teams to follow standard process and tools
 - initially PEL actively sought out teams gaining program approval
 - subsequently teams actively seeking out PEL to support them



AZ Patient Engagement Process for Study Teams

Include Patient Engagement opportunities as part of **early planning**

Patient Engagement Lead (PEL) works closely with clinical team, coordinate meetings and ensures methods selected will address project needs and objectives

PEL designs materials, validated by AZ team and generates summary report

Teams should plan to engage early and ensure funding available

Carefully define objectives and stick to them

Select the best patient insight tool to achieve the objectives

Establish how the impact of patient engagement outputs will be measured

Conduct patient engagement through selected approach

Analyse results and implement the outputs agreed

Measure impact of the changes implemented

Clinical Operations Task Force

Global team will **define key areas of need**:

1. What do they want to understand?
2. What are their risks?
3. What questions can they ask patients?

PEL will promote **learnings across other study teams** and identify opportunities to improve future engagement activities

Targeting all Ph II-III studies

Patient Insights prior to final protocol : example of Methods

Tools	Impact to Patients	Impact for AstraZeneca	Experience to date
<p data-bbox="53 496 231 672">Online patient survey</p> 	<p data-bbox="417 496 1039 611">Patients have the ability to provide:</p> <ul data-bbox="417 625 1014 1053" style="list-style-type: none">• knowledge of living with the disease• how this relates to protocol procedures, visit schedule and medication requirements.	<p data-bbox="1141 496 1549 611">Feedback from patients provides actionable insight to:</p> <ul data-bbox="1141 625 1681 868" style="list-style-type: none">• modify the protocol design• Adjust visit schedule	<p data-bbox="1737 496 2400 611">38% of studies used prior to final design</p>

In 11 of our recent online surveys patients **commented most frequently on visit schedule burden** (frequency, length and time management of appointment); **wanting transportation/travel support; Respect & dignity** (receive own results; feeling of being involved)



Actions Agreed for NSCLC Study

Patient Insights and Recommendations - Action Planning Document

Background: A survey with the Smart Patients online lung cancer patient community was conducted January 2018 in US. The survey instrument was designed by study team and finalized with feedback from the Smart Patients team.

Objective: To receive patient insights to help understand the patients' perspective and preferences for participating in NSCLC research studies – to use these insights to implement appropriate changes to AZ study design & conduct in response to patient preferences.

Summary of Results: Most respondents have not been in a trial and would be open to joining a trial if it were recommended by their physician. They understood the protocol details presented to them.

The concerns raised about the trial included the unknown impact of a placebo arm and the frequency of CT and/or MRI scans.

Top reasons shared that would increase their interest in participating were **travel reimbursement** or other **support with transportation**, receiving a **copy of their test results** and being updated on the **study's progress**.



Targeting all Ph II-III studies

Patient Insights prior to final protocol : example of Methods

Tools	Impact to Patients	Impact for AstraZeneca	Experience to date
<p data-bbox="53 435 359 678">Patient Partnership Program (PPP)</p> 	<p data-bbox="417 435 1034 549">Direct access to individual patients:</p> <ul data-bbox="417 564 1080 1120" style="list-style-type: none">• provide strategic feedback on our key indications (diabetes, asthma, COPD, eosinophil-driven disease, Systemic Lupus, ovarian, and lung cancer)• feedback on operational aspects of study	<p data-bbox="1141 435 1681 549">Direct insights from the individual patient:</p> <ul data-bbox="1141 564 1630 928" style="list-style-type: none">• In-depth and quality feedback• Two way conversation with the patients allows clarification of Qs/As	<p data-bbox="1737 435 2433 614">11% of the studies in AZs key indications have worked with the PPP to gain insight</p>

In 2 of our recent Patient Partnership discussions patients **commented most frequently on study drug administration** (timing, length, SOC vs placebo); **financial support** (patient's own finances); **Perception & opinion of clinical studies affecting patient participation**



Actions Agreed for Ovarian Cancer Study

Patient Insights and Recommendations - Action Planning Document

Background: A Patient Partnership Program (PPP) was conducted with 3 ovarian cancer patients in December 2017.

Objective: To determine patient acceptance of the study assessments and patient materials

Feedback Included: Comments were received on the **timing of background chemotherapy infusion** as time indicated in the protocol did not compare to actual patient experiences, which were much longer.

Patient feedback also reinforced that the **informed consent was too long (25 pages)** and that it would help patients to better understand the study requirements if a **short overview of the study** was provide.

Patients wanted to make AZ aware that at this time patients are receiving a lot of new information so anything the study team can do to make this easier for understanding and processing of information is appreciated.

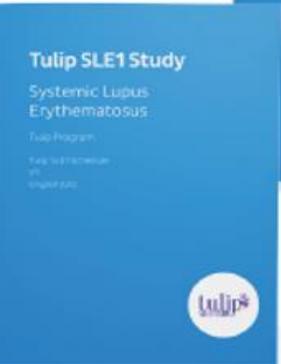
Summary of agreed actions:

1. Clarify protocol procedures:
 - a. **Updated chemotherapy dose timing** information so patients have a better understanding of how long they will be in the chemotherapy unit on treatment days.
 - b. **Revised the informed consent** to keep as short and concise as possible



Targeting all PhII-III studies

Patient Engagement activities - example of tools

Tools	Impact to Patients	Impact for AstraZeneca	Experience to date
<p>TRACE (patient visit guide)</p> 	<p>Booklet or Web Portal:</p> <ul style="list-style-type: none"> • Complements the Informed Consent process • Informs patients about the study in everyday language (procedures and visit schedule) • used by the patient throughout the study to keep them on track. 	<p>Before signing ICF patients are better informed:</p> <ul style="list-style-type: none"> • about the expectations of the clinical study • potential for increased retention. 	<p>46% of studies Over 6900 patients</p>

During a patient discussion to gather feedback, “The Informed Consent makes me feel like a patient while the TRACE booklet makes me feel like a person”.



Targeting all PhII-III studies

Patient Engagement activities-example of tools

Tools	Impact to Patients	Impact for AstraZeneca	Experience to date
<p>PLM TrialMark (Patient Experience Survey)</p> 	<p>Gather insight from patients on their experience whilst in the study:</p> <ul style="list-style-type: none">• to fix current study issues when data is available in real-time• to make changes for future programs (e.g. phase II informs phase III)	<p>Survey to gather patient insight on their experience in the study.</p> <p>Direct feedback from patients Create best practice design in new trials based on patient insight.</p>	<p>Pilot study currently ongoing</p>



Insights before final protocol: Impact of putting patients first

SCLC1 Study Patient Engagement Activities

-in-depth patient/site interviews

-patient centric questions in feasibility

Optimize Protocol design

- ❖ Patient insights consider operational aspects of study conduct vs. design optimization.
- ❖ Reduce number of scans or examinations (e.g., scan done just prior to study enrolment could be re-used in study)

Enhance site conduct of study procedures

- ❖ Explore options for Home Visits

Enhance clarity of study documents for patients

- ❖ Simplified Patient Consent Form
- ❖ TRACE booklet/website made available
- ❖ Other patient facing tools (study leaflets)

Improve study experience for patients

- ❖ Explore option with sites to **improve patients comfort** during site visit (held **workshop at IM**)
- ❖ Explore **travel services** for sites to offer to patients and **upfront reimbursement** to patients for travel expenses e.g Vendor offering 'uber taxi' services for patient travel to site visits

Improve study experience for sites

- ❖ AZ study app for sites

Targeting all PhII-III studies

Patient Engagement activities-example of tools

Tools	Impact to Patients	Impact for AstraZeneca	Experience to date
Patient Engagement App 	Easy access for the patient to <ul style="list-style-type: none">• visit reminders,• tracking of study drug,• Study specific measurements• dosing instructions	More engaged patient for better retention	Pilot study ongoing

Interim report for the Pilot study shows that 94% of the patients report the purpose of the study is clear to them and 68% of patients felt that they were provided with important information during the study



Studies have meaningful changes to protocol design and conduct

Phase 2b Type-2 Diabetes Mellitus - Various patient engagement opportunities

Optimize Protocol design	<ul style="list-style-type: none">❖ Simplify visit procedures (reduced blood draw, reduced number of PRO administrations);❖ Included the TrialMark patient experience survey (US and Canada)❖ Consider home delivery of study meds for subjects
Enhance site conduct of study procedures	<ul style="list-style-type: none">❖ Develop a study portal for sharing study documents and information with AZ monitors and site staff.❖ Additional tools implemented on Study portal: e.g. visit guide, visit calculator.
Enhance clarity of study documents for patients	<ul style="list-style-type: none">❖ Simplified and reduced Consent Form to 14 pages❖ Implement TRACE trial booklet/website for all countries and sites in local languages. Enhance booklet to include illustrations, pictures for procedures❖ Provide patients with digital app to be installed on patients' own mobile devices (or devices provided by AZ) - launched Dec 2017
Improve study experience for patients	<ul style="list-style-type: none">❖ Liaise with local teams to develop action plan for each site to support patient travel arrangements and site re-imburement❖ Provision of subject trial experience survey – for patients to give feedback on general experience of the study (pilot for English-speaking patients only). Implemented at 4 timepoints during the study (ongoing analysis – aim to improve design/conduct of Ph3 studies and apply to other TAs)



Considerations

- Including Patient Insights requires early planning – particularly for new TA/indication
- Funding – depending on the approach used the cost can be considerable (50-200K USD)
- Feedback/interaction tends to be in English – restricts global understanding of patient care/needs
- AZ are expanding opportunities – including UK's new NIHR offering with FTF patient meetings



Moving Patient Centricity to Business as Usual

- **Optimize protocol design by enabling uptake of patient insights into Clinical Study Protocol**
 - Maximize patient interaction for all Phase II – III studies supported by Patient Engagement Lead
 - Ensure sharing knowledge between teams to enable proactive improvements to our protocols
- **Increase internal communication about Patient Insights & Patient Engagement tools**
 - Widely share Patient Insights used across studies – can be used to support UK submissions
 - Include details of patient centricity methods and outcomes during study feasibility kick off meetings
 - Continue to promote incorporation of insights and engagement tools into future Study Planning
 - Enhanced internal communication of the positive impact on our protocols from Patient Insights
 - Improved lessons learnt and sharing of these more widely



