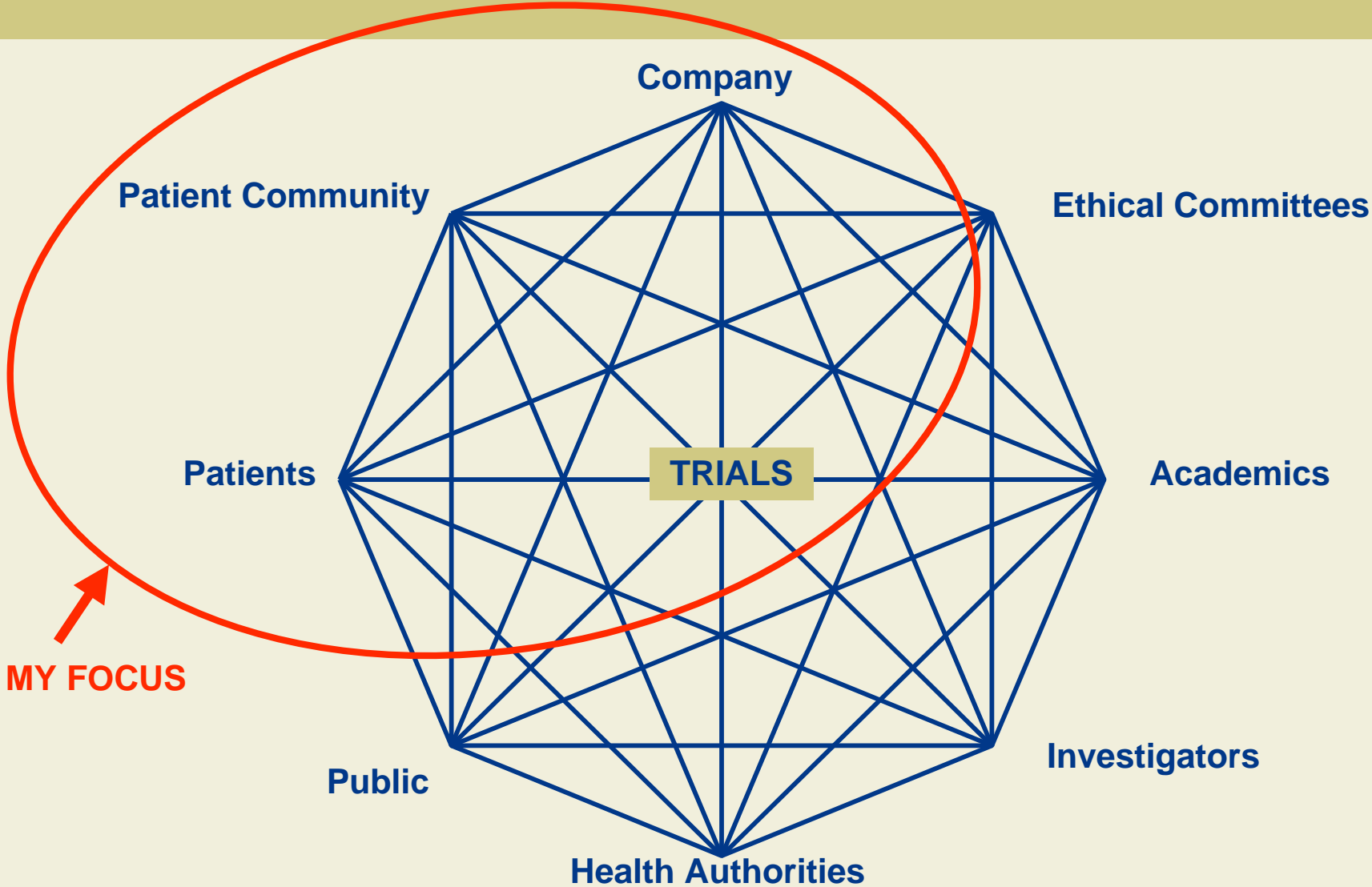


Patients Participation in Clinical Trials



Daniel De Schryver
Director Community Affairs

Stakeholders discussed today



Patient as an individual



A patient in a Clinical Trial



- First important element: participating can save lives!
- “Healthy Volunteer” vs “Patient with a disease”
 - » Both are individual people
 - » Helping science
 - » Looking for solutions for themselves & others
 - » Access to new treatments
- Questions a patient asks:
 - Risks?
 - » Side-effects / Placebo
 - Costs?
 - Terminology in Informed Consent Form (ICF)

People Living with HIV/AIDS





Evolution of PLWHA community



- Denial of disease in the 80's has led to strong protest.
 - Highly educated community
 - Pre-existing social networks (MSM)
- Internet has made their networks very efficient.
- Pandemic: global issue, everyone feels involved.
- From a deadly disease to a chronic disease.

Patient community



Community structure



- Several local/national groups
 - Support, education, prevention
- European Aids Treatment Group
 - Founded in 1991; Co-operative structure
 - Treatment activists from 31 European countries
- European Community Advisory Board (EATG project)
 - promote the harmonization of good clinical practice, standard of care and access
 - » Review clinical trial design at planning stage...
 - » Represent and defend patients interest in clinical trials...
 - » Suggest new developments in HIV treatment

Other roles in Clinical Trials



- Defend patient's interest
 - As an individual and as a group
- Fight for broad access
 - To new trials
 - To new medicine
- Sharing Information (through web and other)
 - Opening & recruiting trials (www.clinicaltrials.gov)
 - Published data
- Educate community members

Tibotec



Our philosophy



- Tibotec worked since the beginning on principles of:
 - Partnering
 - Dialogue
 - Transparency
- Continued with Johnson & Johnson, in line with credo.
- Newcomer: early R&D and patient involvement
 - Other pharma companies had to learn by mistakes

Concrete examples



Concrete examples



- Patient involvement in clinical trials through:
 - Protocol design and review
 - Informed Consent review
 - DSMB (Drug Safety Monitoring Board) involvement
 - Investigator Meeting participation
- Feedback beyond the trials:
 - Urgency to include other investigational agents in our clinical trials
 - Early Access Programs (EAP), Compassionate Use
 - Insisting on a global perspective
 - Reinforcing the need for responsible pricing

How does it work?



What is reviewed



- Protocol and ICF review
 - All Phase IIb and Phase III Tibotec Trials
 - All Company Sponsored Phase IIIb and Phase IV
 - Protocol review has priority over ICF.

Operating procedure



- Within Tibotec Global Clinical Development department:
 - Internal procedure for Community to review ICF templates
Relevant project-specific forms e.g. Phase III trials, ...
 - Active trigger to reflect upon appropriateness of community involvement built into SOPs and Work Instructions (WIs)
- Process to ensure feedback is looked at on a cross-project basis

Working Principles (1)



- Working Principles in place with ECAB & ATAC DDC:
 - Yearly contracts with EATG for ECAB reviews, and with ATAC
 - ECAB/ATAC to appoint reviewers
 - Number of community reviewers from any organization limited to 5
 - Completion of review within 5 business days
 - Collation of comments in 1 feedback document, to which we respond
 - » Tibotec response on the protocol to occur within 14 days
 - » Tibotec response on the ICF to occur within 30 days
 - » Coordination of feedback through Professional/External Affairs

Working Principles (continued)



- Working Principles in place with ECAB & ATAC DDC:
 - Compensation at hourly rate for hours of active review
 - Payments are made directly to organization
 - Common understanding that with some consistency of reviewers, total time investment decreases
 - Prerogative to limit number of participants and/or total amount of time invested in any given review

More types of involvement



- Advisory Boards:
 - Moment of reflection on appropriateness is in SOP
- Drug Safety Monitoring Boards (DSMB's)
- Investigator Meetings
- Investigator Webcasts
 - Informed on issues

Beyond these examples



- Bi-yearly meeting with ECAB
- Discussions include but are not limited to trials

Conclusion



- Active patient involvement in Clinical Trials is possible and *positive for both parties*, if:
 - Long-Term relation is built to ensure trust and confidence;
 - Patient Community representation is organised;
 - Strong organisational structures exist (SOP's);
 - Patient literacy is ensured to optimise feedback;
 - Mutual acceptance exists of limits to what can be achieved;
 - Strict confidentiality can be ensured.