Hypothetical Scenario: Working Toward Solutions

September 18, 2014 Mark Barnes

Objectives

Review the hypothetical scenario to identify:

- Fundamental areas of agreement
- Areas of complexity
- Derive key challenges that may be addressed by a new Harvard MRCT initiative regarding post-trial access

the hypothetical scenario may be found in your folders

Summary of Hypothetical Scenario

- Ministry of Angola collaborates with a Belgian biotech BelgiqueTec that has rights to a diabetes drug and seeks to test it in clinical trials
- Angolan government contributes $25M to finance trials in Angola
- In-kind commitment of resources from Angola study sites
- Incidence of diabetes in the population has been increasing
- Agreement- Ph I and Ph II trials to be conducted in

Results of Hypothetical Scenario

- No Phase I adverse effects
- 200 Angolan citizens with moderate to severe diabetes enrolled in Phase II; all treatment-naive
- Phase II – half show improvement in diabetes control
- However, decreased cardiac function in 3 subjects associated in time with drug administration

Key Questions for Panel

- If based on the AEs, drug development is halted, what is the obligation of BelgiqueTec and MOH to continue to deliver diabetes treatment of any kind to the Phase II subjects?
    - Experimental drug or standard of care?
    - For how long?
- Should AEs and secondary complications be treated and who should pay?
- Would it matter if in the ICF, participants were told that there would be no follow up care provided?

Key Questions for Panel

Currently over 1000 patients awaiting treatment at the Luanda clinic/hospital, some more serious than the study participants

- Should the 200 research subjects have priority over these 1000 on the waiting list?

Should BelgiqueTec be expected use its limited resources to expand the clinics resources to enable care for the 200 subjects as an incremental treatment group?

What if doing so means that BelgiqueTec could not afford to develop its two other promising diabetes drugs, but instead would purchase an annuity and close up shop?

Does the scenario change if a large pharmaceutical company is involved ?

Key Questions for Panel

Should we therefore expect Angola to use its own resources to treat these 200 participants in the Luanda clinic? This would divert funds from other Angola health/public health purposes.

Do answers differ based on the host country? What if this took place in the US or in a more resource-poor nation than Angola?

Key Questions for Panel

If lifetime care should be provided, should downstream costs (hospitalization, amputation etc.) be included? What is the scope of care required?

If the test drug appears efficacious but more expensive than similarly effective alternative treatments, can a less costly treatment be provided as part of the post-trial access provision?

Continued duty to provide the test drug even though it will not be developed further? What if cost to produce is huge?

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