Introduction of new drugs/regimens in Vietnam

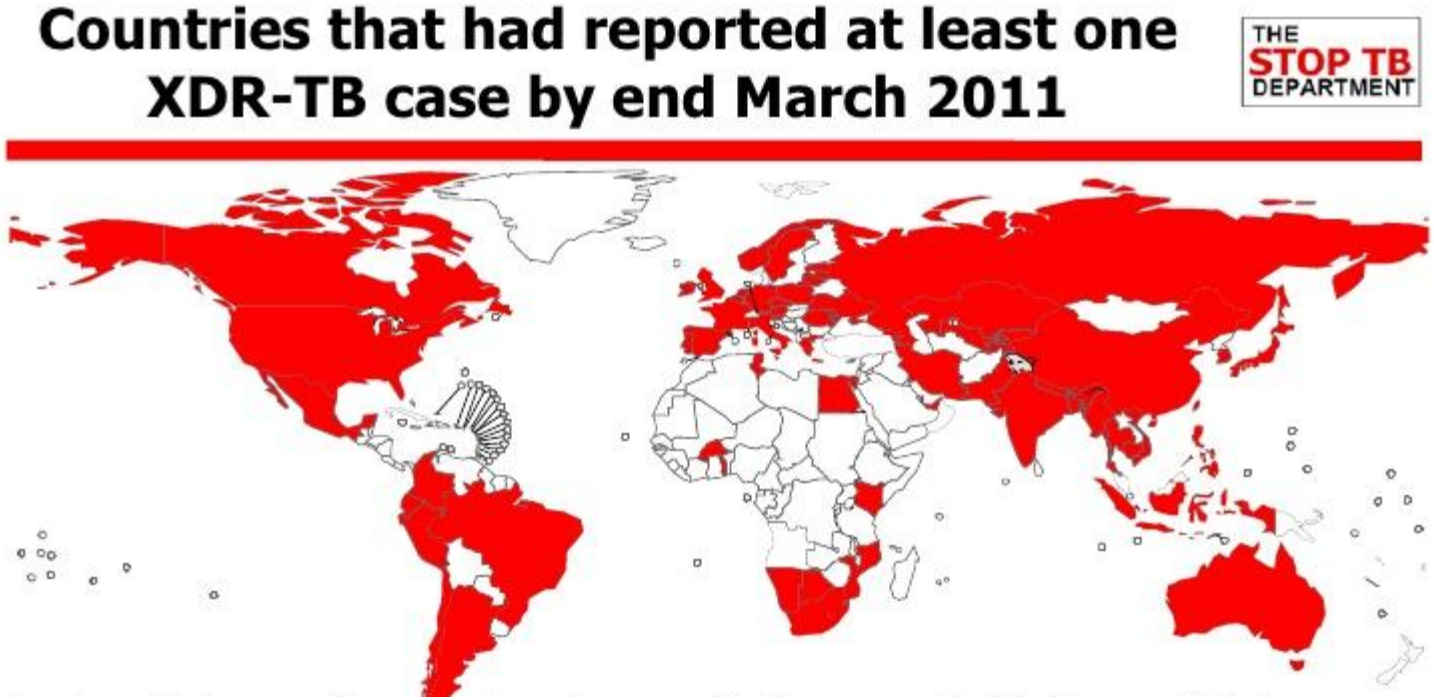
DRTB STAT call, April 2017

Situation of Drug-resistant TB in Viet Nam

	DRS 3 (06-07)	DRS 4 (11-12)
MDR rate among new TB patients	2.7 % (2.0-3.6%)	**4.0 % (2.5 - 5.4%)**
MDR rate among retreated patients	19% (14-25%)	**23.3% (16.7-29.9)**
The number of MDR-TB patients among the number of new TB patients every year	2000 (1500-2700)	3000
The number of MDR-TB patients among the number of retreated patients every year	1700 (1200-2200)	2100
Total number of MDR-TB patients among total number of TB patients every year	3700	5100
XDR-TB/MDR-TB		**5.6%**
FQ res/MDR-TB		**16.7%**

+ MDR-TB/pre XDR-TB/XDR-TB

Global TB report (2016)
- 580.000 new cases MDR-TB/RR-TB
- 9,5% among MDR-TB: XDR-TB



Treatment of MDR/preXDR/XDR in Việt Nam:

→ Conventional reg. and shorter reg. for MDR-TB

→ Estimated 868 cases preXDR/XDR per year → limited treatment options (new drugs are under research)

DRTB in Vietnam:
- Estimated yearly : 5.200 cases MDR-TB/RR-TB
- 16,7% FQs resistance among MDR-TB
- 5,6% XDR-TB among MDR-TB

MDR-TB RESPONSE (PMDT program)

- **Progress:**
  - 2007: GLC's approval
  - 2009: pilot in Ho Chi Minh city
  - Until Dec/2016: Total **about 8.500** patients were enrolled,
  - Treatment success rate: **more than 70%**
  - **101 pts enrolled in shorter regimen (cohort study)**
  - **99 pts enrolled in Bedaquiline individualized regimen (cohort study)**
- **Current status:**
  - PMDT coverage: 63/63 provinces
  - PMDT guidelines: updated with recent recommendations
  - Training materials available for different target groups.
  - Xpert MTB/RIF coverage: 100% provinces
  - SLDs LPA: 2 labs → will cover all R+ cases detected in 2017

Rationale for new drugs and regimens in DR-TB treatment

RR/MDR-TB: 5.200 cases among notified; significant number of patients have been enrolled (30%/year). However:

- There is no regimen for MDR-TB patients (>850 cases) who:
  - Have failed MDR-TB treatment (7%)
  - XDR-TB patients (5.6%)
  - FQ resistance (16.7%)
  - Intolerance to current second-line drugs

  → New drugs required

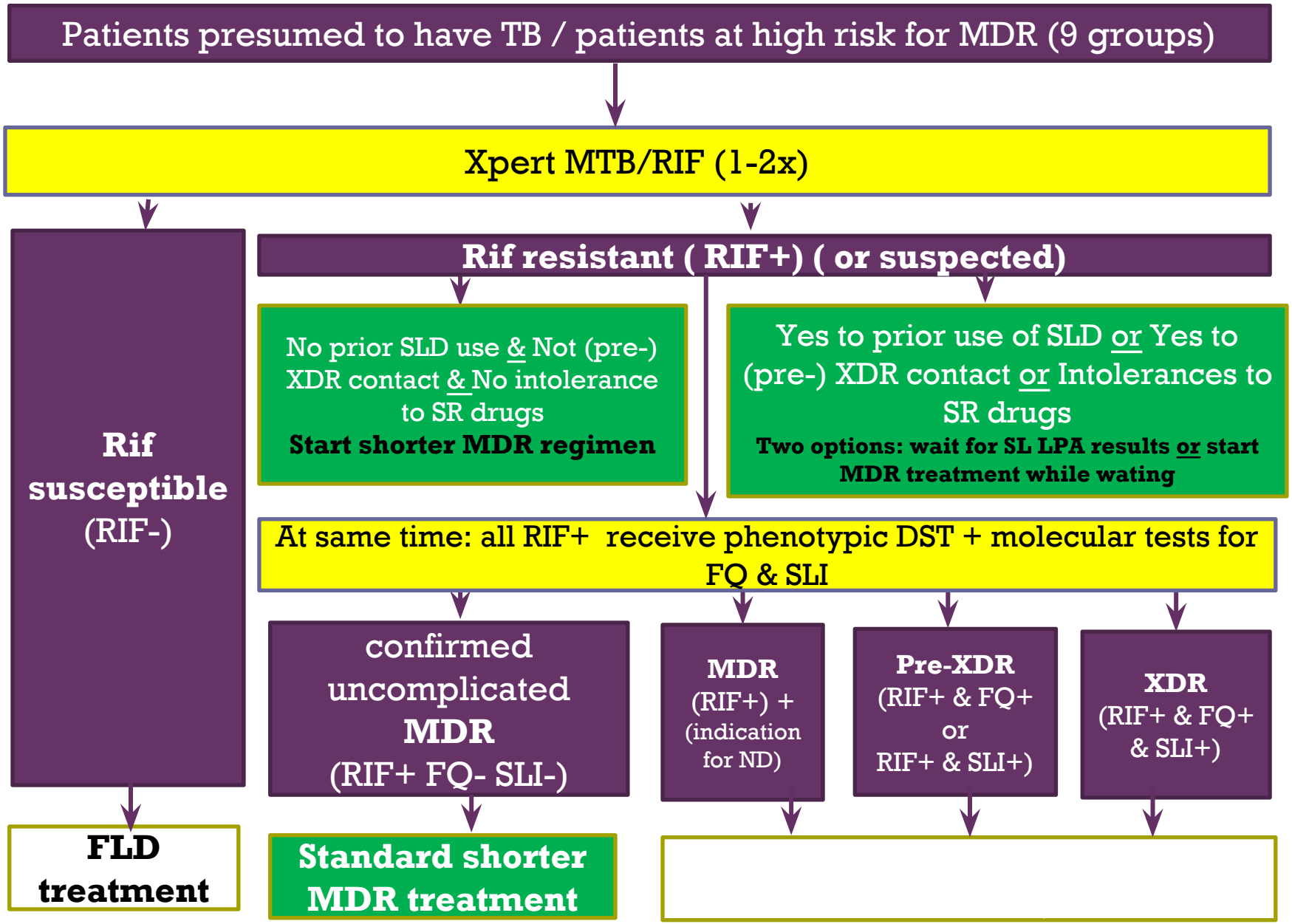
- Current regimen (20 months): lost to follow up >10% (long course, AEs → short course regimens with effectiveness and safety required

Brief introduction about STR and BDQ cohort study

- **Aim:** To assess the new drug containing regimen and new regimen for
  - **Efficacy** (conversion rate, cured rate)
  - **Safety** (AEs, lost to follow up, regimen changes)
- **Sites:** 3 cities Hanoi, Hochiminh city, Cantho
- **Number of patients recruited:** 100/each study
- **Inclusion criteria:**

BDQ regimen	Shorter regimen
- Resistance to second line drugs: injectable or/and FQs - Intolerance to existing regimen	Resistance to R, **not to** second line drugs

New D&T algorithm – patient triage approach

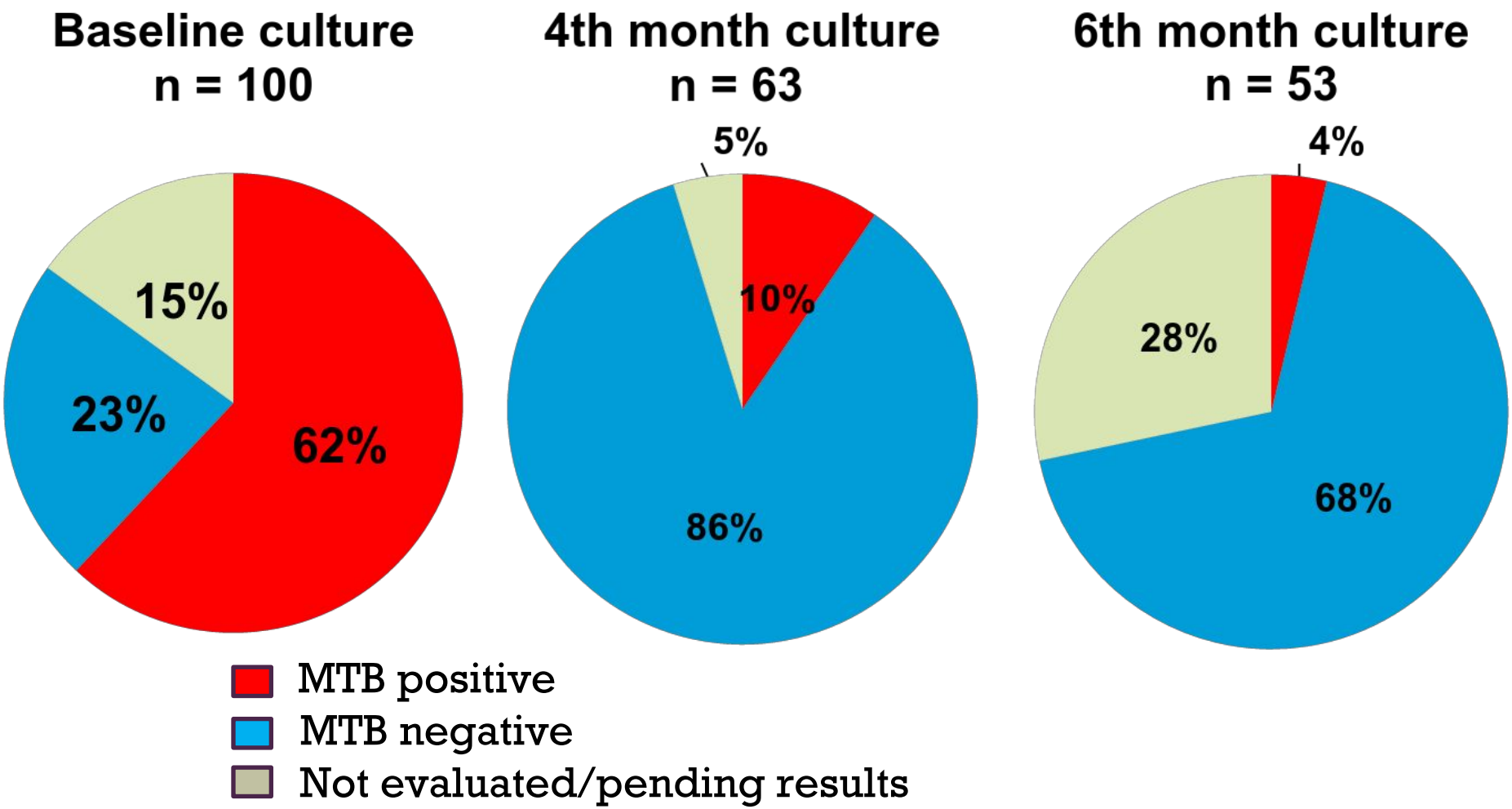


SL LPA testing in Vietnam

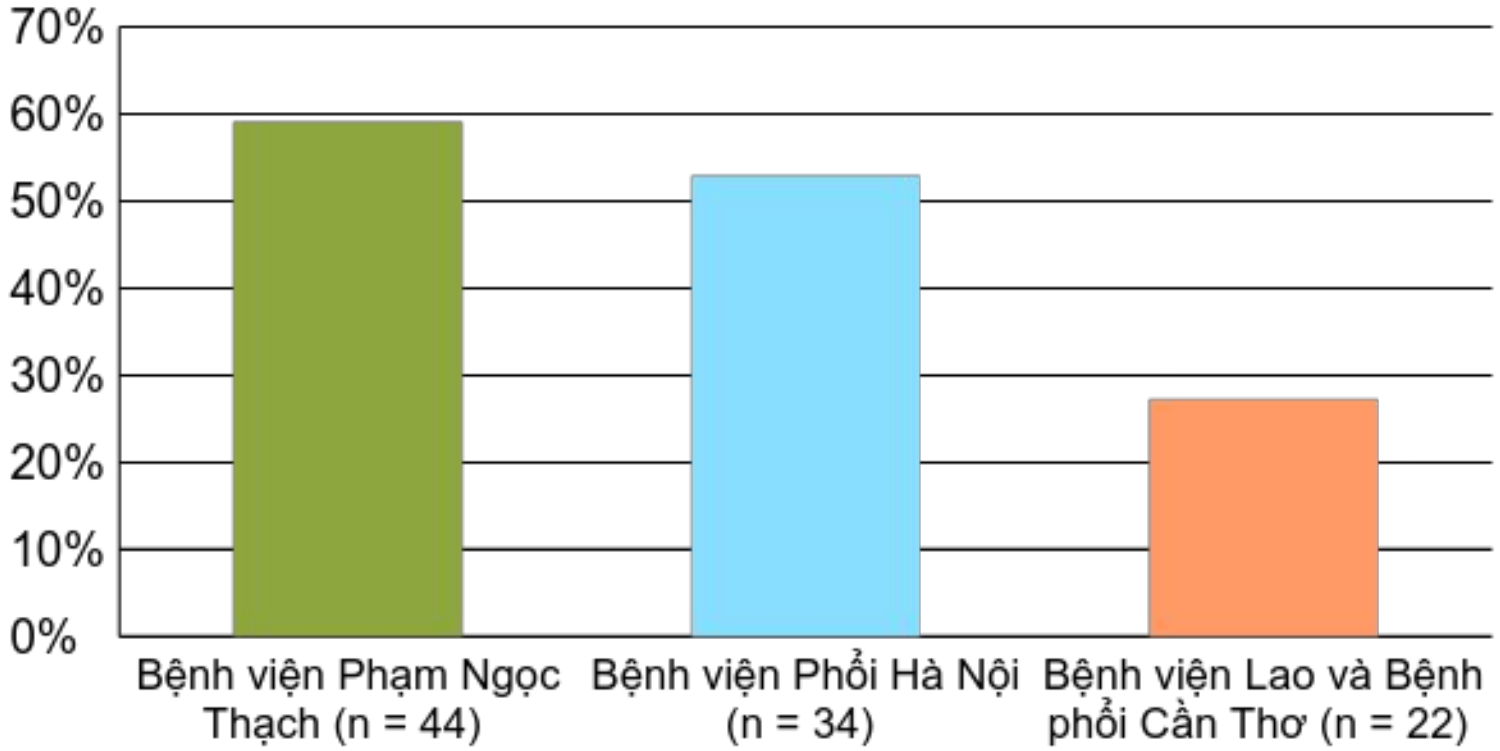
- Started from October 2015 with version 1, currently using version 2
- 2 labs: NRL (Hanoi), PNT lab (Hochiminh city)
- From Oct15 – Dec16: at 3 pilot sites, SL LPA for all RR detected, presumptive preXDR/XDR-TB
- **2016 data:** from 3 sites, 524 cases tested with SL LPA:
  - Res. to FQs = 69
  - Res. to SL injectables = 19
  - Res. to both = 19
  - Total 107
  - Enrolled 85 cases in BDQ treatment
- From 2017: SL LPA for:
  - all RR detected in 19 sites,
  - presumptive preXDR/XDR-TB in all PMDT site

+ STR cohort (1)

total 101 patients enrolled



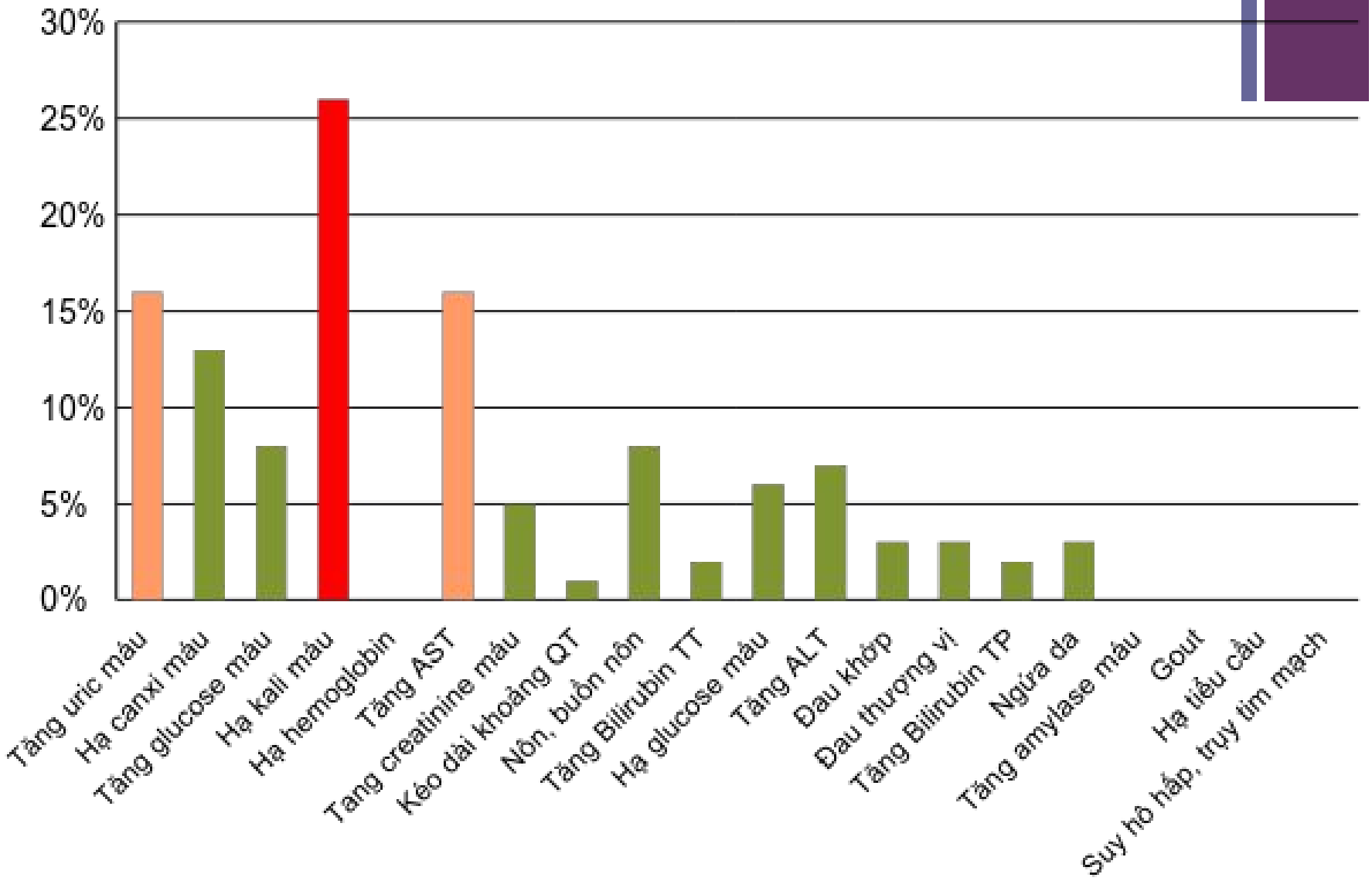
STR cohort (2)
proportion of any AEs



Sites	No of pts with any AEs	Proportion of any AEs
BV Phạm Ngọc Thạch (n = 44)	26	59,09%
BV Phổi Hà Nội (n = 34)	18	52,94%
BV Lao và Bệnh phổi Cần Thơ (n = 22)	6	27,27%
n = 100	**50**	**50%**

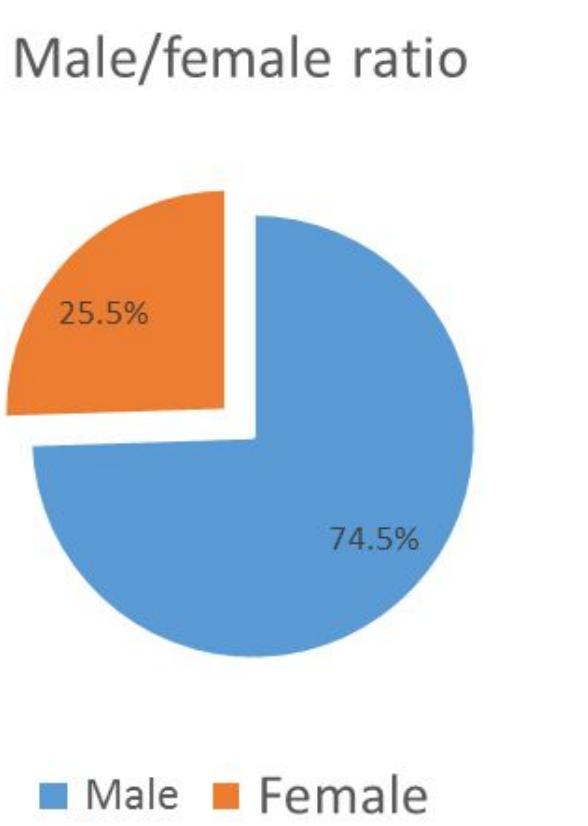
STR cohort (3)

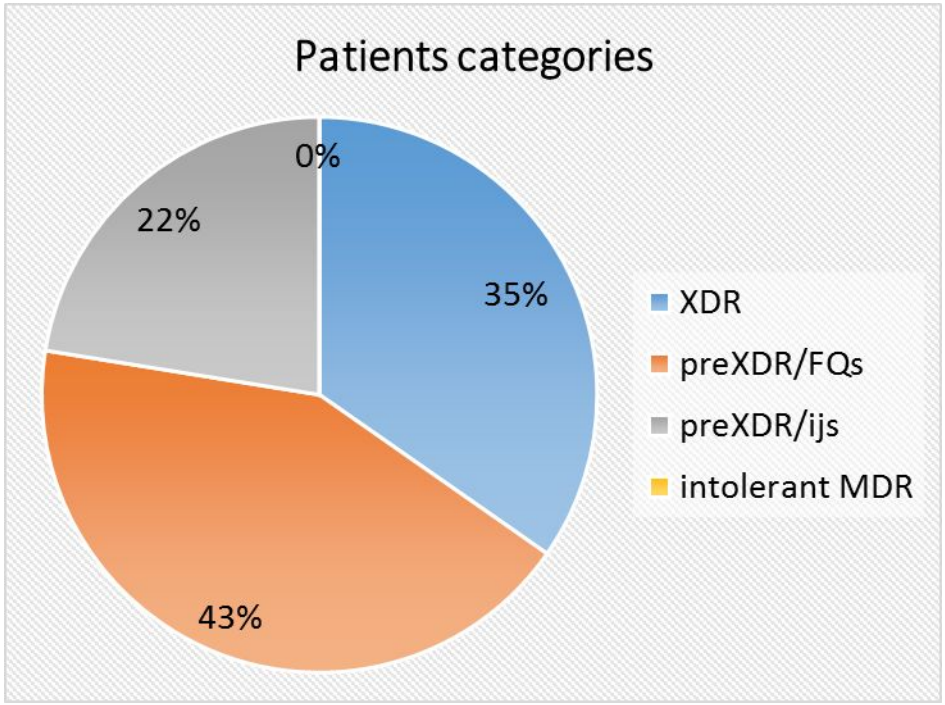
Proportion of different AEs



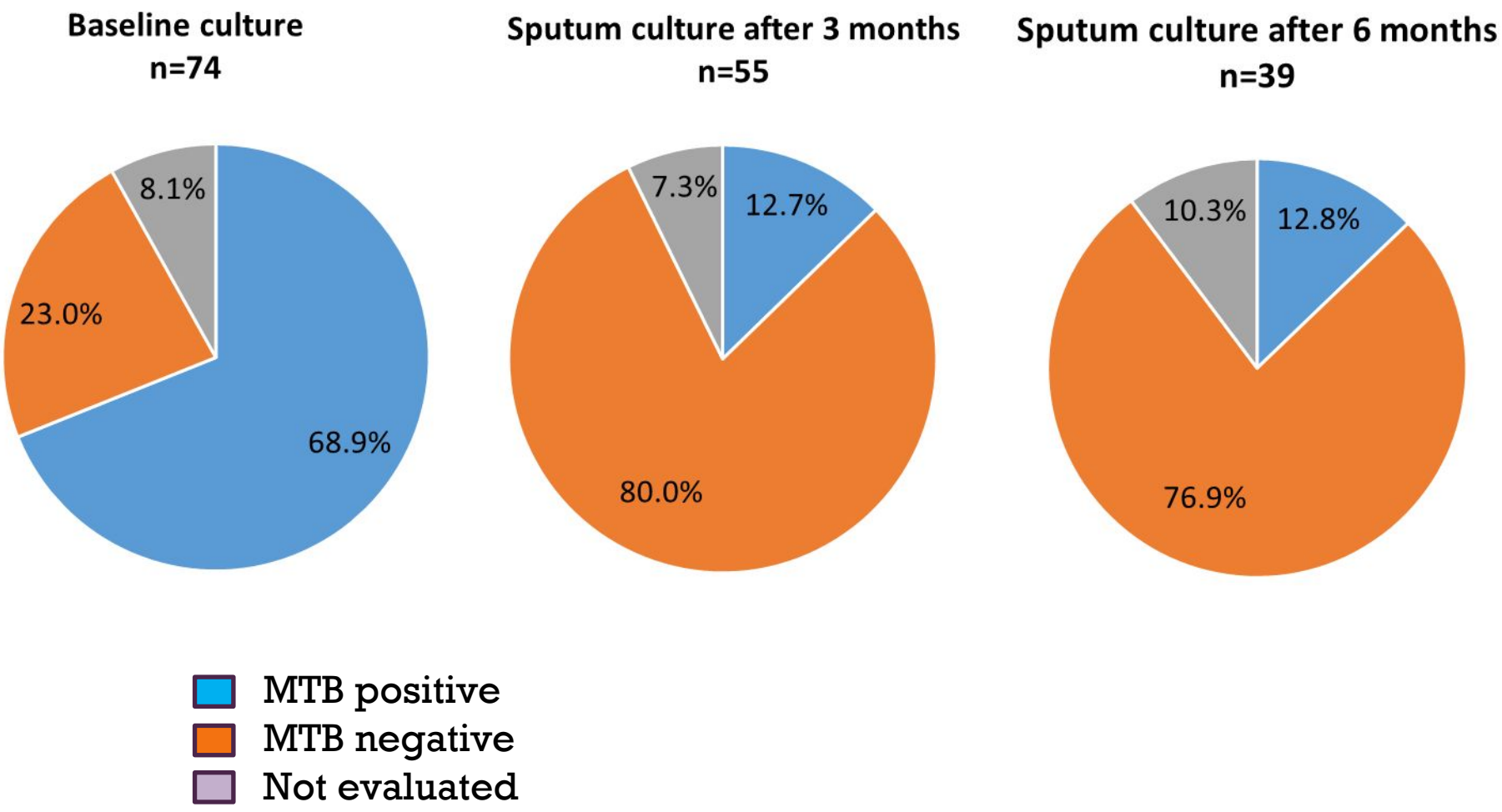
BDQ cohort (1)

Dec15 - Mar17, total = 99 patients





BDQ cohort (2)
sputum culture conversion

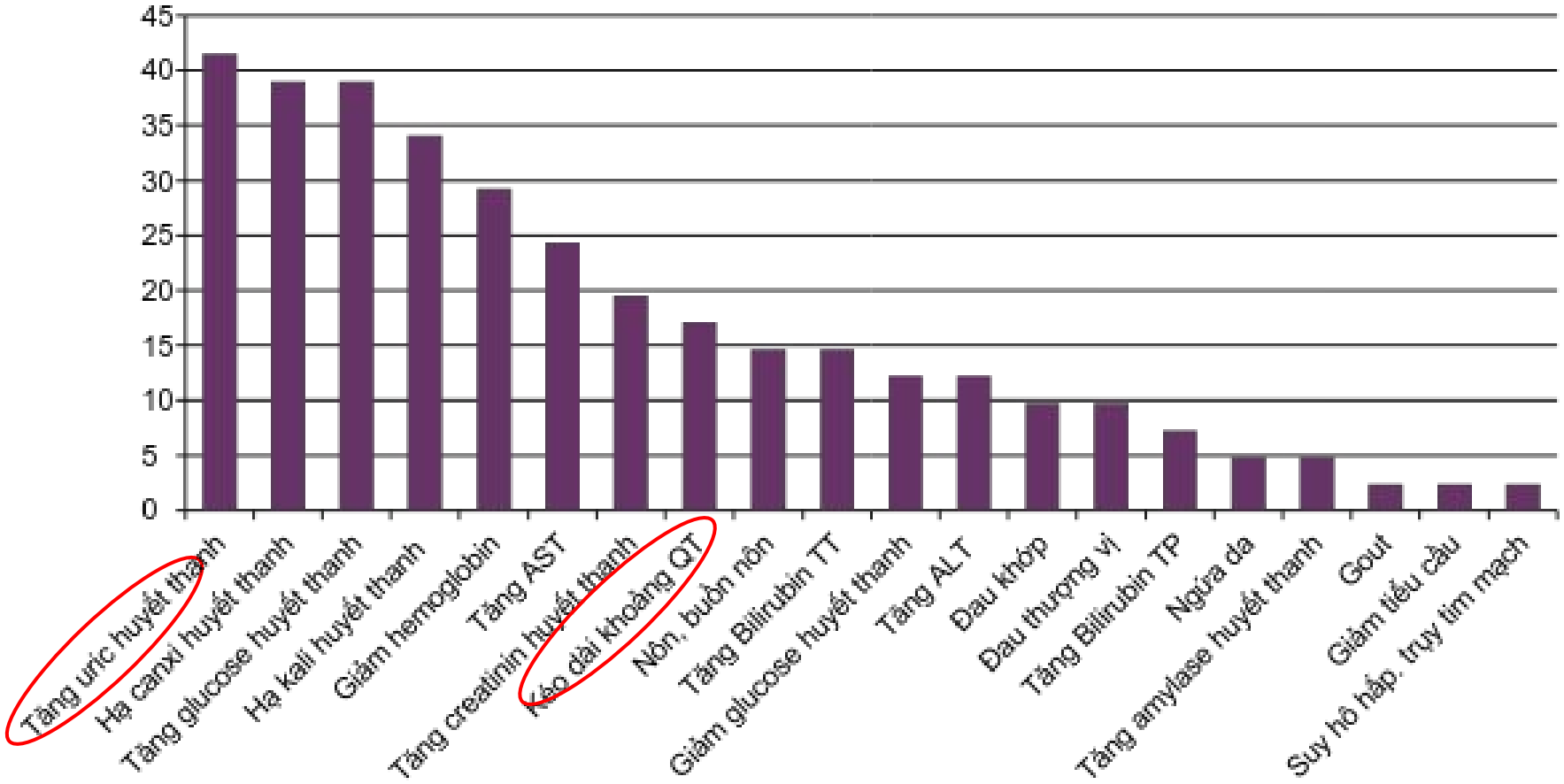


BDQ cohort (3)

Initial results of safety

N = 41 patients (evaluation after 6 months)

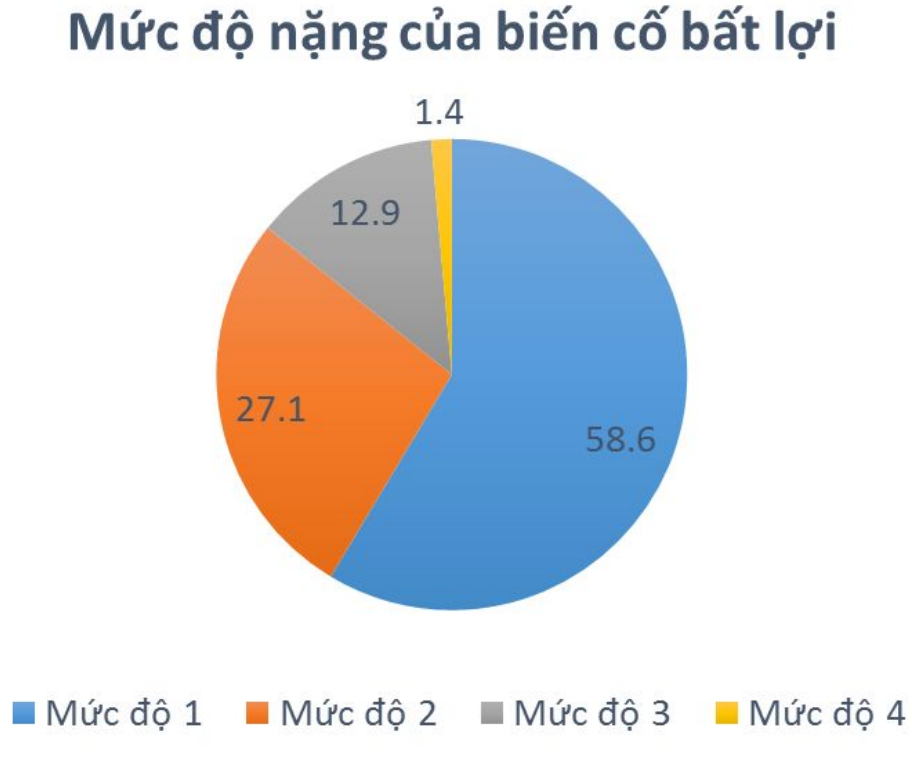
Proportion of different Adverse Events



+ BDQ cohort (4)

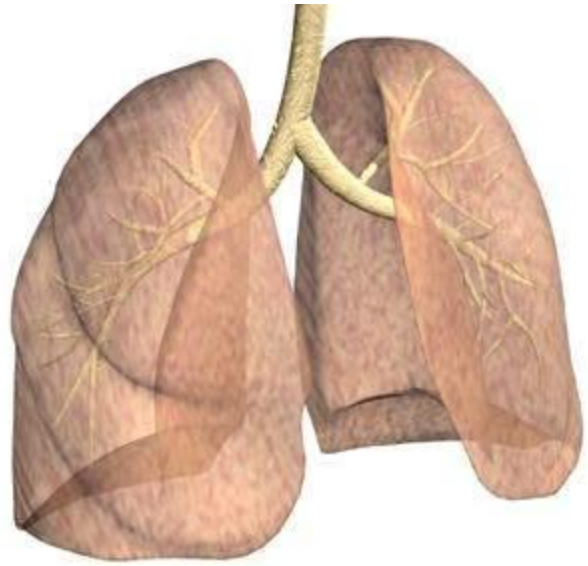
Initial results of safety

N=41



11,4% changed treatment regimen (treatment interruption/ dose adjustment/ stop treatment)

THANK YOU VERY MUCH



For your attention!