TAHOD
HIV Observational Database

TREAT Asia
HIV Observational Database
(TAHOD)

Therapeutics Research • Education • AIDS Training
TREATASIA

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Background

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- A cooperative network of clinicians throughout Asia and the Pacific that aims to expand capacity for the broader introduction of HIV/AIDS treatments in the region

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- A multi-centre, observational study of patients with HIV
- Aims to assess HIV disease natural history in treated and untreated patients in the Asia and Pacific region.

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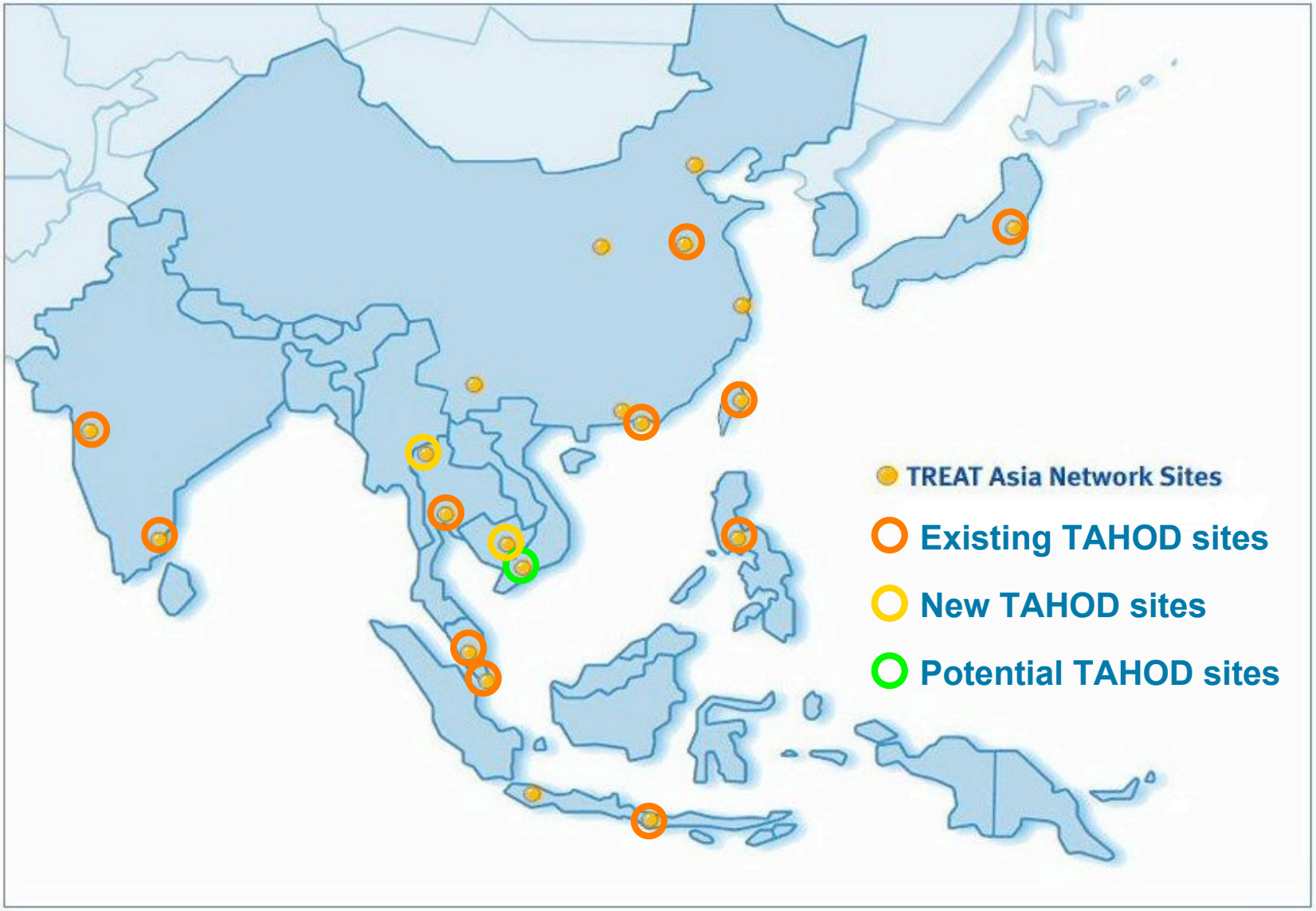

March 2006

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Site selection

- A number of sites were involved with TREAT Asia
- Devised a site survey
  - Distributed to all sites
  - Gauged interest and ability to comply with TAHOD study methods
    - Electronic data transfer - email
    - Initial 3 year commitment
    - Local ethics approval
- Aimed for broad representation across the region
- Initially 11 participating sites in the Asia and Pacific region
  - 13 from September 2004
  - 15 from September 2005

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Patient selection

- Patient recruitment
  - Can't hope to recruit patients that are entirely representative
    - Not a surveillance mechanism
  - Scientifically better to get good, consistent data on a limited number of patients that can be reliably followed-up

  - Target of 200 patients per site
  - Consecutive series of regularly attending patients
  - Stratified by antiretroviral treatment
    - Balances random sampling with need for good follow-up

  - Gives good data on HIV disease natural history

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- TAHOD population
  - Male 71%
  - Non-pediatrics, patients 18 years or older
  - Urban patients
  - Centers for excellence
  - Public funded population
- Toxicity data are collected for research purposes
- Data are collected electronically in Microsoft Excel format
  - Transferred to NCHECR
  - Compressed in Winzip format

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Patient demographics

Male		71%
Age (years) mean (SD)		36 (9.9)
range		18- 90 years
Exposure:	MSM	18%
	IDU	4%
	Hetero	64%
	Other/NK	14%
CD4 (cells/mm^3) mean (SD)		307 (229)
HIV (copies/ml) median (IQR)		400 (400–8,900)
Prior AIDS		41%
ARVs: HAART		77%
Mono/double		2%
None		21%

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Toxicity data collection

- Data specification version 1
  - Reason for treatment cessation
  - Laboratory tests
    - Haemoglobin, ALT
- Data specification version 2 (beginning March 2006)
  - Grade 3-4 clinical adverse events
    - AACTG criteria
  - Additional laboratory tests
    - When collected according to local site practice

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Adverse events

- CARDIAC
- CLINICAL HEPATITIS
- DEPRESSION/ANXIETY
- DIABETES
- DIARRHOEA
- FAT ACCUMULATION
- FATIGUE
- FRACTURE
- IMMUNE RECONSTITUTION SYNDROME (IRS)
- LACTIC ACIDOSIS (DEFINITIVE & PRESUMPTIVE)
- LIPOATROPHY
- NAUSEA/VOMITING
- PANCREATITIS
- PERIPHERAL NEUROPATHY
- RASH
- RENAL STONE
- STROKE
- OTHERS
- UNKNOWN

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Laboratory tests

- Blood pressure (systolic and diastolic)
- Haemoglobin
- Cholesterol, fasting
- HDL, fasting
- Glucose, fasting
- Triglycerides, fasting
- Blood amylase,
- Blood creatinine
- Lactate
- Lipase
- Alkaline phosphatase
- ALT
- SGPT, SGOT
- Bilirubin

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Toxicity data collection

- Toxicity data are to be collected prospectively for research purposes
- Data are collected in Microsoft excel format and transferred to NCHECR for central aggregation and analysis
  - Every 6 months
- TAHOD Steering Committee fully support the collaboration of research into long-term monitoring of treatment related adverse events in the resource limited settings