NECT FIELD

Phase IIIb Trial.

Primary efficacy and in-hospital safety results

ISCTRC September 14, 2011

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DNDi

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Study objectives

- Primary objective
  - –Assess the **clinical response** of NECT under field conditions (discharged alive from the hospital*)
- Secondary objectives:
  - –Assess the incidence and type of **adverse events** (AE), and the capacity of the treatment centers to deal with these
  - –Assess the **feasibility** of the implementation of NECT by the health center
  - –Assess the **effectiveness** of NECT at 24 months after treatment

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Study design

- Multicentre, open-labelled, non-controlled
  - –All stage 2 HAT patients (diagnosed according local rules)
    - Pregnant/breastfeeding women, small children
    - Other underlying disease, poor health, old age
    - At the decision of investigator or national rules
  - –Target sample size: 620 patients
  - –DSMB and stopping rule
  - –Study duration 12 months (enrolment)
    - Follow up: for each patient 24 months (6, 12, 18, 24 months)

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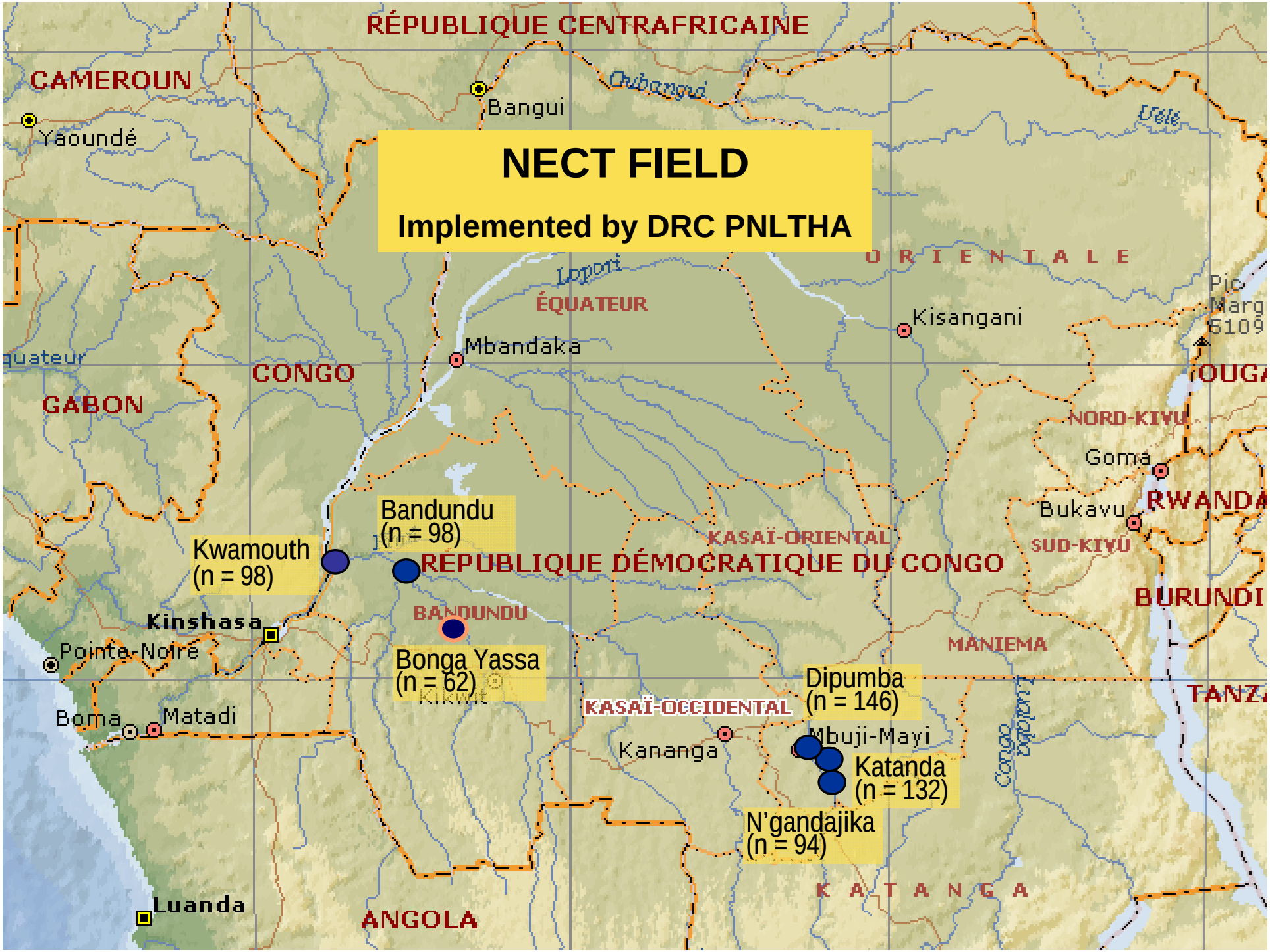
NECT FIELD
Implemented by DRC PNLTHA
RÉPUBLIQUE CENTRAFRICAINE
CAMEROUN
Bangui
Yaoundé
Oubangui
Uélé
ORIENTALE
Lopori
ÉQUATEUR
Kisangani
Mbandaka
CONGO
GABON
NORD-KIVU
Goma
Bukavu
RWANDA
Bandundu
(n = 98)
Kwamouth
(n = 98)
KASAÏ-ORIENTAL
SUD-KIVU
RÉPUBLIQUE DÉMOCRATIQUE DU CONGO
BURUNDI
BANDUNDU
Kinshasa
Pointe-Noire
MANIEMA
Bonga Yassa
(n = 62)
Dipumba
(n = 146)
KASAÏ-OCCIDENTAL
Boma
Matadi
Kananga
Mbuji-Mayi
Katanda
(n = 132)
N'gandajika
(n = 94)
Luanda
ANGOLA
KATANGA

Results

Patient Characteristics	n	%
Patients treated	629	
Children 0 to 4 years	33	5
Children 5 to 11 years	64	11
Pregnant women	13	2
Breastfeeding women	34	5
Patients who previously had HAT	135	21
Sex ratio (male: female)		1.3
Age, mean (SD)	29,6	(16,2)
Body Mass Index <18.5 (undernourished)	249	40

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Results

HAT Diagnosis	n	%
CATT + (median titer 1/32)	546	87
Trypanosome detected in any compartment	559	89
White Blood Cell count, mean (SD)	261	(331)

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Primary efficacy

- Patients discharged alive: 98.4%
- Karnofski scale index improvement after treatment. (16% from 70 to 86)
- Reduced clinical signs and symptoms
  - Lympadenopathy 54% to 22%
  - Neurological 89% to 37%
- Similar improvement across special age groups pregnant or breastfeeding women

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Adverse Events

	NECT FIELD (in hospital safety) (N=629)	NECT (Priotto 2009) (N=143)	DFMO (Priotto 2009) (N=143)
Average adverse events per patient	4	5	5
Patients having at least one Adverse event	578 (92%)	95%	96%
Severe Adverse Event (CTC grades 3-5)	77 (12%)	14%	29%
Serious Adverse Event (SAE)	32 (5.1%)	0.7%	4%
Fatalities	10 (1.6%)	0.6%	2.1%
Treatment cessations	5 (0.8%)	1.4%	8%

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Mortality (in-hospital safety)

- SEX: 4 male and 6 female.
- AGE: Average 42, range 18 to 77.
- DATE: Average after treatment start 12 days. Range 2-23
  - 3 complex infections (2 respiratory; 1 septic shock)
  - 3 non specific diagnosis (1 sudden death)
  - 2 developed coma
  - 1 anaemia
  - 1 cardiogenic shock.
- Confusing mortality analysis as symptoms were related with disease in a background of severely ill (at least 5 cases) and often malnourished patients.

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Most Common Adverse Events %	All n=629	Children n=100	Pregnant / Breast feeding n=47	Other patients n=482
Gastro-intestinal	**61**	**43**	**74**	**64**
Vomiting	43	31	63	44
Nausea	20	13	11	22
General disorders	**46**	**57**	**70**	**42**
Fever	30	44	39	26
Asthenia	18	13	37	17
Nervous system	**34**	**21**	**33**	**37**
Headache	14	8	17	16
Vertigo	10	0	9	13
Convulsions	9	10	7	9

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Most Common Adverse Events %	All n=629	Children n=100	Pregnant / Breast feeding n=47	Other patients n=482
Metabolic	**26**	**22**	**17**	**28**
Anorexia	25	21	15	27
Psychiatric	**16**	**9**	**9**	**18**
Agitation	6	5	9	6
Insomnia	6	3	0	8
Musculoskeletal (pain)	**14**	**4**	**17**	**15**
Respiratory	**10**	**7**	**9**	**11**
Skin disorders	**9**	**9**	**7**	**10**
Pruritus	7	6	7	7

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Conclusions

- 629 patients, often in poor general health condition, treated with NECT
- In-hospital survival rate: data in field conditions (98.4%) similar to that observed in NECT clinical trial
- No new safety signal, especially in children

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Thanks to

Donors:

Department for International Development (DFID) / UNITED KINGDOM
Ministry of Foreign and European Affairs (MAEE) / FRANCE
Republic and Canton of Geneva, Department International Solidarity / SWITZERLAND
Spanish Agency for International Development Cooperation (AECID)/ SPAIN
Swiss Agency for Development and Cooperation (SDC) / SWITZERLAND
Médecins Sans Frontières (Doctors without Borders) / INTERNATIONAL
Medicor Foundation / LIECHTENSTEIN
and others who would like to remain anonymous.

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