Aus dem Institut für Tropenmedizin
der Medizinischen Fakultät der Charité – Universitätsmedizin Berlin

DISSERTATION

Ansprechen auf antiretrovirale Therapie in einer ländlichen Region in West-Uganda

Zur Erlangung des akademischen Grades
Doctor medicinae (Dr. med.)

vorgelegt der Medizinischen Fakultät der Charité – Universitätsmedizin Berlin

von Anne-Lena Weide

aus Stuttgart

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INHALT

ERKLÄRUNG AN EIDES STATT

„Ich, Anne-Lena Weide, erkläre, dass ich die vorgelegte Dissertationsschrift mit dem Thema: *Ansprechen auf antiretrovirale Therapie in einer ländlichen Region in West-Uganda* selbst verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel benutzt, ohne die (unzulässige) Hilfe Dritter verfasst und auch in Teilen keine Kopien anderer Arbeiten dargestellt habe.“

05. Februar 2007 Anne-Lena Weide

LEBENSLAUF

Mein Lebenslauf wird aus Datenschutzgründen in der elektronischen Version meiner Arbeit nicht mit veröffentlicht.

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ANHANG: Dokumentationsbögen

ART Programme Uganda

First visit

Patient registration number: ____

PMTCT number: ____

Date: ____

A) Demographics

Name: ____ **Village:** ____

Surname: ____ **Subdistrict:** ____

Sex: ☐ Female ☐ Male **Age:** ____ years

Ethnic group: ☐ Mutooro ☐ Mukiga ☐ Munjankole ☐ other

Religion: ☐ Moslem ☐ Catholic ☐ Protestant ☐ other

Occupation: ☐ Housewife ☐ Farmer ☐ Business men/women ☐ Without occupation ☐ Other occupation

Education: ☐ None ☐ Primary school ☐ Secondary school ☐ Tertiary school

Home distance to Buhinga Hsp: ☐ Less than 30 km ☐ More han 30 km

B) Medical History

HIV test: Date HIV test: ____ dd/mm/yy

Last CD4 count: Absolute number: ____ /µl Percentage: ____ %

Date CD4 count: ____

Last Viral load (children): Last Viral load: ____ Date Viral load: ____

Have any HIV related events ever occurred? (several answers possible)

☐ Lymphadenopathy ☐ Herpes Zoster ☐ Pruriginous dermatitis

☐ Oral candidiasis ☐ Prolonged fever more than 1 month ☐ Kaposi sarcoma

☐ Oral hairy leukoplakia ☐ Weight loss more than 10 % ☐ Tuberculosis

☐ Severe bacterial infection (pneumonia, pyomyositis) ☐ Chronic diarrhea more than 1 month

If other, specify: ____

____

Any other current chronical disease? ☐ Yes ☐ No

If yes, specify: ____

____

Any drugs currently taken? ☐ Yes ☐ No

Drug 1: ____ Dose 1: ____

Drug 2: ____ Dose 2: ____

ART Programme Uganda | First visit

Patient registration number: ____ Date ____ dd/mm/yy

C) Current symptoms (several answers possible)

☐ **Fever** If yes,temperature: ____ °C Since when ? ____ days

☐ **Weight loss** If yes, current weight: ____ kg Percentage of weight loss: ____ %

☐ **Skin changes** ☐ Rash ☐ Kaposi sarcoma ☐ Other

Describe: ____

Since when ? ____ days

☐ **Mucosal damage** ☐ Thrush ☐ Ulcers ☐ Kaposi sarcoma ☐ Other

Describe: ____

Since when ? ____ days

☐ **Lymphadenopathy** ☐ Cervical ☐ Inguinal ☐ Other

Describe : ____

Since when ? ____ days

☐ **Pulmonary symptoms** ☐ Dry cough ☐ Productive cough ☐ Dyspnoea ☐ Chest pain ☐ Other

Describe: ____

Since when ? ____ days

☐ **Cardiovascular symptoms** ☐ Arrhythmia ☐ Hypertonus ☐ Other

Describe: ____

Since when ? ____ days

☐ **Abdominal symptoms** ☐ Abdominal pain ☐ Vomiting ☐ Obstipation ☐ Other

Describe: ____

Since when ? ____ days

☐ **Diarrhea** ☐ Bloody diarrhea Frequency per day: ____ / day

Since when ? ____ days

☐ **Genital symptoms** ☐ Discharge ☐ Ulcers ☐ Warts ☐ Other

Describe:

Since when ? days

☑ **Urinary tract symptoms** ☐ Dysuria ☐ Alguria ☐ Bloody urine ☐ Other

Describe:

Since when ? days

☐ **Neurological disorders** ☐ Sensoric disorders ☐ Motoric disorders ☐ Cognitive disorders

☐ Other

Describe:

Since when ? days

☐ **Psychatric disorders** ☐ Depression ☐ Hallucinations ☐ Psychosis

☐ Vivid dreams ☐ Other

Describe:

Since when ? days

☐ **Musculosceletal symptoms** Describe:

Since when ? days

☐ **Other symptoms** If yes, describe:

Since when ? days

☐ **Other symptoms** If yes, describe:

Since when ? days

D) Laboratory examinations (compulsary)

Complete blood count

WBC:	/µl	RBC:		Hb:	g/dl
MCV:	fl	PLT:		Hct:	%
Lymphocytes:	/µl	Neutrophiles:	/µl		
Eosinophiles:	/µl	Basophiles:	/µl	Monocytes:	/µl

Serum chemistry

SGOT: U/l Lipase: U/l GGPT: U/l

Creatinine: mg/dl Glucose: mg/dl CPK: U/l

Current CD4 count + Viral load (children)

Date CD4 count : dd/mm/yy

CD4-Percentage: % CD4-absolute number: / µl

Viral load (children): c/ml Date Viral load : dd/mm/yy

Urine analysis (please indicate only, if positive)

☐ Glucose / urine ☐ Proteine ☐ Erythrocyte ☐ Nitrite ☐ Leukocyte

Microscopy: Result:

Other examinations

RPR / TPHA: ☐ RPR positive If RPR positive, perform TPHA titer:

☐ RPR negative

Sputum smear: Result:

Pregnancy test: ☐ Positive ☐ Negative

E) Further examinations (optional)

Further laboratory examinations

Type of examination: Result :

Type of examination: Result :

Type of examination: Result :

Type of examination: Result :

Smears

☐ Blood smear Result :

☐ Urethra smear Result :

Other smear, specify: Result :

X

Further laboratory examinations

☐ Biopsy	Location of biopsy:		Result :	
☐ Stool examination			Result :	
☐ X-Ray	Location of X-Ray:		Result :	
☐ Ultrasound	Region:		Result :	
Other examination, specify:			Result :	

F) Diagnosis

☐ **Asymptomatic HIV infection**

☐ **Symptomatic HIV infection, specify:**

☐ Acute TB ☐ Herpes Zoster ☐ Chronic diarrhea more than 1 month

☐ Wasting ☐ Pruriginous dermatitis ☐ Oral hairy leukoplakia

☐ Oral candidiasis ☐ Kaposi sarcoma ☐ Pneumonia

☐ Prolonged fever of unknown origin more than 1 month

☐ Other severe bacterial infection — Specify bacterial infection:

Other diagnosis, specify: — Other diagnosis, specify:

Other diagnosis, specify:

☐ **Other disease,specify:**

☐ UTI ☐ Malaria

☐ STD — Specify STD:

☐ Anemia — Specify anemia:

☐ Hepatitis — Specify hepatitis, if possible:

☐ Other disease — Specify diesease :

G) Treatment

(without antiretroviral treatment)

Treatment indicated ? ☐ Yes ☐ No

Admission to hospital ? ☐ Yes ☐ No

Diagnosis 1:		Medication / Consequences	
Diagnosis 2:		Medication / Consequences	
Diagnosis 3:		Medication / Consequences	

H) Tuberculosis

Acute Tuberculosis ?	☐ Yes	☐ No
If no, INH comb. prophylaxis prescribed?	☐ Yes	☐ No

I) OI-Prophylaxis

HIV prophylaxis indicated ?	☐ Yes	☐ No	
If yes, which drug(s) ?	☐ Cotrimoxazole	Dosage:	
	☐ Other drug	Name + Dosage other drug:	

J) Exclusion criteria

Indicate, if any exclusion criteria exists:

☐ Severe mental illness impeding drug intake ?

☐ Pregnancy in women

If any exclusion criteria currently existent, no enrollment of the patient !

Summary forms complete ?	☐ Yes	☐ No
ART patient card delivered to patient?	☐ Yes	☐ No
Informed consent and ART information delivered to patient ?	☐ Yes	☐ No
Date new visit (in 2 weeks):		

In case of acute TB or any other severe illness (e.g. opportunistic infections) the next visit ("ART programme enrolment") has to be delayed (on an individual basis). Continue with next visit as soon as ARVT is possible!

ART Programme Uganda

Programme enrolment

Patient registration number

Date: dd/mm/yy

- page 1 -

A) HIV data

Last CD4 count:

CD4 / Absolute number: / µl Percentage: %

Date CD4 count: dd/mm/yy

Current Viral load:

Current viral load: c / ml Date viral load: dd/mm/yy

Both measurements indiating treatment ? ☐ Yes ☐ No

If "no", no programme enrolment! Control of CD4 count and VL in 4 weeks!

Please indicate current HIV CDC/WHO stage: HIV CDC / WHO stage:

B) Antiretroviral treatment indication

Antiretroviral treatmen indicated ?

☐ **No** If no, why not ?

☐ Acute TB ? ☐ Non-advanced HIV stage ?

☐ Other ? If other, specify:

☐ **Yes** If yes, indication based on: (several answers possible)

☐ CD4 count ☐ Viral load ☐ Clinical stage (CDC/WHO stage C)

ART Programme Uganda | Programme enrolment

Patient registration number ____ Date: ____ dd/mm/yy

C) Programme enrolment

Inclusion criteria: (All answers have to be "yes" ! If not, no programme enrolment !)

HIV test positive ?	☐ Yes	☐ No
Informed consent signed ?	☐ Yes	☐ No
ARV treatment indicated ?	☐ Yes	☐ No

For women only:

Current use of contraceptives ?	☐ Yes	☐ No
Refraining from breastfeeding ?	☐ Yes	☐ No

All questions answered as "no" ? ☐ Yes ☐ No

For women only:

Currently used method of contraception ? ☐ IUCD ☐ Injectable contraceptive ☐ Norplant

Progamme enrolment ? ☐ Yes ☐ No

Date of enrolment: ____ dd/mm/yy

ART Programme Uganda

Programme enrolment

Patient registration number ☐ Date: ☐ dd/mm/yy

D) Antiretroviral drug regimen

Standard drug regimen

Contraindications to standard regimen

Are there any contraindications or reasons impeding use of standard regimen ? ☐ Yes ☐ No

If yes, specify:

☐ Severe mental illness ?
☐ Liver cirrhosis ?
☐ Anemia (Hb < 7,5 g/dl) ?
☐ History of pancreatitis ?
☐ Neutropenia (< 750 / µl)
☐ Other contraindication ? If other , specify: ☐

In case of contraindications, choose alternative antiretroviral drug regimen (next page) !

Standard drug regimen **Only for adults ! For children, indicate regimen next page !**

Please tick choosen regimen! (once daily - regimen, if last digit of patient registration number is even. Twice daily - regimen, if the last digit is uneven).

☐ Twice daily - regimen

Combivir 2 x1 pill / day (AZT 2 x 300 mg + 3TC 2 x 150 mg)

+

Efavirenz 1x3 pills/day (EFV 1 x 600 mg)

Pill intake twice daily: 1 pill in the morning and 4 pills in the evening independent of food intake.

☐ Once daily - regimen

Epivir 1 x 1 pill / day (3TC 1 x 300 mg)

+

Videx 1 x 1 pill / day ☐ > 60 kg / 1 x 400 mg

+ ☐ < 60 kg / 1 x 250 mg

Efavirenz 1x3 pills/day (EFV 1 x 600 mg)

Pill intake once daily: 5 pills in the evening, 2 hours after dinner.

Note: in case of coadministration of rifampin (rifampicin) as TB treatment the dosage of Efavirenz has to be increased to 4 pills / day (EFV 1 x 800 mg in the evening) !!

ART Programme Uganda | Programme enrolment

Patient registration number ____ Date: ____ dd/mm/yy

Alternative antiretroviral regimen: (Tick, which drugs are eligible. Indicate dosage, if other than standard dosage)

Nucleosidale reverse transcriptase inhibitors (NRTI):

☐ Zidovudine (AZT) 2 x 300 mg	If other dosage, indicate:	
☐ Didanosine (DDI) 1 x 400 mg	If other dosage, indicate:	
☐ Stavudine (d4T) 2 x 40 mg	If other dosage, indicate:	
☐ Lamivudine (3TC) 1 x 300 mg	If other dosage, indicate:	
☐ Abacavir (ABC) 2 x 300 mg	If other dosage, indicate:	
☐ Combivir (AZT + 3TC)		
☐ Trizivir (AZT + 3TC + ABC)		

Non-nucleosidale reverse transcriptase inhibitors (NNRTI):

☐ Nevirapine (NVP) 2 x 200 mg	If other dosage, indicate:	
☐ Efavirenz (EVF) 1 x 600 mg	If other dosage, indicate:	

Protease inhibitors (PI):

☐ Indinavir (IDV) 3 x 800 mg	If other dosage, indicate:	
☐ Nelfinavir (NFV) 2 x 1250 mg	If other dosage, indicate:	
☐ Amprenavir (APV) 2 x 1200 mg	If other dosage, indicate:	
☐ Saquinavir sgc (SQV/sgc) 2 x 1600 mg	If other dosage, indicate:	
☐ Lopinavir/Ritonavir (LPVr) 2 x 400/100 mg	If other dosage, indicate:	

Protease inhibitor-combinations:

☐ Ritonavir / Saquinavir hgc (RTV/SQV-hgc) 2 x 100/1000 mg	If other dosage, indicate:	
☐ Ritonavir / Indinavir (RTV/IDV) 2 x 100/800 mg	If other dosage, indicate:	
☐ Ritonavir / Amprenavir (RTV/APV) 2 x 100/600 mg	If other dosage, indicate:	

Other drug 1:		Dose drug 1:	
Other drug 2 :		Dose drug 2:	

Summary forms complete? ☐ Yes ☐ No

Date new visit (in 2 weeks): ____ ***Signature:*** ____

ART Programme Uganda | Follow-up visit

Patient registration number

PMTCT number

Name: Surname: Date dd/mm/yy

- page 1 -

Pleae indicate, if:

☐ **Routine follow up visit**

☐ 2 weeks	☐ 4 month	☐ 12 month	☐ 21 month
☐ 1 month	☐ 6 month	☐ 15 month	☐ 24 month
☐ 2 month	☐ 9 month	☐ 18 month	☐ 27 month

Or:

☐ **Additional follow up visit** (VL and CD4 optional)

A) Current symptoms (several answers possible)

☐ **Fever** If yes,temperature: °C Since when ? days

☐ **Weight loss** If yes, current weight: kg Percentage of weight loss: %

☐ **Skin changes** ☐ Rash ☐ Kaposi sarcoma ☐ Other

Describe:

Since when ? days

☐ **Mucosal damag** ☐ Thrush ☐ Ulcers ☐ Kaposi sarcoma ☐ Other

Describe:

Since when ? days

☐ **Lymphadenopathy** ☐ Cervical ☐ Inguinal ☐ Other

Describe :

Since when ? days

☐ **Pulmonary symptoms** ☐ Dry cough ☐ Productive cough ☐ Dyspnoea ☐ Chest pain ☐ Other

Describe:

Since when ?

ART Programme Uganda | Follow-up visit

Patient registration number _____ Date _____ dd/mm/yy

☐ **Cardiovascular symptoms** ☐ Arrhythmia ☐ Hypertonus ☐ Other

Describe: _____

Since when ? _____ days

☐ **Abdominal symptoms** ☐ Abdominal pain ☐ Vomiting ☐ Obstipation ☐ Other

Describe: _____

Since when ? _____ days

☐ **Diarrhea** ☐ Bloody diarrhea Frequency per day: _____ / day

Since when ? _____

☐ **Genital symptoms** ☐ Discharge ☐ Ulcers ☐ Warts ☐ Other

Describe: _____

Since when ? _____

☐ **Urinary tract symptoms** ☐ Dysuria ☐ Alguria ☐ Bloody urine ☐ Other

Describe: _____

Since when ? _____

☐ **Neurological disorders** ☐ Sensoric disorders ☐ Motoric disorders ☐ Cognitive disorders

☐ Other

Describe: _____

Since when ? _____

☐ **Psychatric disorders** ☐ Depression ☐ Hallucinations ☐ Psychosis

☐ Vivid dreams ☐ Other

Describe: _____

Since when ? _____

☐ **Musculosceletal symptoms** Describe: _____

Since when ? _____

☐ **Other symptoms** If yes, describe: _____

Since when ? _____

☐ **Other symptoms** If yes, describe: _____

Since when ? _____

ART Programme Uganda | Follow-up visit

Patient registration number ____ Date ____ dd/mm/yy

B) Adherence to antiretroviral drugs

Regular intake of antiretroviral pills since last follow up ?

☐ Yes ☐ No How many doses were missed?: ____ doses

How many days with regular pill intake last week ?

☐ All days ☐ 6 of 7 days ☐ 5 of 7 days ☐ 4 of 7 days
☐ 3 of 7 days ☐ < 3 of 7 days

How many doses were missed last week ?

☐ None ☐ 1 dose ☐ 2 doses ☐ 3 doses
☐ 4 doses ☐ > 4 doses

How many pill doses were not taken according to time and food schedule ?

☐ None ☐ 1 dose ☐ 2 doses ☐ 3 doses
☐ 4 doses ☐ > 4 doses

Reasons for imperfect pill intake ? (several answers possible)

☐ Pills too expensive ☐ Intake schedule too complicated
☐ Intake forgotten ☐ Bad taste

☐ drug adverse event / toxicity Specify adverse event: ____
☐ Other reason Specify reason: ____

C) Laboratory examinations

Note: The following examinations are obligatory for routine follow up visits, but only optional for additional follow up visits !

Complete blood count

WBC:	/µl	RBC:		Hb:	
MCV:	/µl	Thrombocytes:		Hct:	%
Lymphocytes:	/µl	Neutrophiles:	/µl		
Eosinophiles:	/µl	Basophiles:	/µl	Monocytes:	/µl

Pregnancy test ☐ Positive ☐ Negative

Serum chemistry

SGOT:	U/l	Lipase:	U/l	GGPT:	U/l
Creatinine:	mg/dl	Glucose:	mg/dl	CPK:	U/l

Urine analysis (please indicate only, if positive)

☐ Glucose / urine ☐ Proteine ☐ Erythrocyte ☐ Nitrite ☐ Leukocyte

Microscopy: Result:

Viral load:	c/ml	Date viral load:	
CD4 count absolute number:	/ µl	CD4 count percentage:	%
		Date CD4 count:	

Note: CD4 count only at month 2, 6, 9, 12, 15, 18, 21,24, 27; Viral load determination only at month 2, 6, 12, 18, 24; CD4 count and viral load are optional for extra follow visits (for example: recommended if suspected treatment failure)

D) Additional laboratory examinations

(please indicate type of additional examination + result)

Type of examination:		Result :	
Type of examination:		Result :	
Type of examination:		Result :	
Type of examination:		Result :	
Type of examination:		Result :	

ART Programme Uganda | Follow-up visit

Patient registration number: ____ Date: ____ dd/mm/yy

E) Contraception

For women only !

Current use of contraceptives ?

☐ Yes If yes, indicate method: ☐ IUCD ☐ Injectable contraceptive ☐ Norplant

☐ No If no, start new contraception. Otherwise exclude patient from study!

Indicate new method: ☐ IUCD ☐ Injectable contraceptive ☐ Norplant

F) Diagnosis

(several answers possible)

☐ **Asymptomatic HIV infection**

☐ **Symptomatic HIV infection, specify:**

☐ Acute TB ☐ Herpes Zoster ☐ Chronic diarrhea more than 1 month

☐ Wasting ☐ Pruriginous dermatitis ☐ Oral hairy leukoplakia

☐ Oral candidiasis ☐ Kaposi sarcoma ☐ Pneumonia

☐ Prolonged fever of unknown origin more than 1 month

☐ Other severe bacterial infection Specify bacterial infection: ____

Other diagnosis, specify: ____ Other diagnosis, specify: ____

Other diagnosis, specify: ____

☐ **Drug related toxicity**

☐ Hepatitis ☐ Gastrointestinal intolerance ☐ Diabetes mellitus

☐ Lipodystrophy ☐ Hyperlipidemia ☐ Pancreatitis

☐ Rash ☐ Peripheral polyneuropathy ☐ Hypersensitivity reaction

☐ Psychatric disorders ☐ Lactic acidosis ☐ Nephrolithiasis

☐ Other toxicity 1 Specify 1: ____

☐ Other toxicity 2 Specify 2: ____

Suspected drug 1: ____ Suspected drug 3: ____

Suspected drug 2: ____

☐ **Teatment failure**

☐ **Other disease** Specify disease 1:

Specify disease 2:

G) HIV CDC / WHO stage

Please indicate HIV stage. It may have changed due to changes in VL, CD4 count and / or clinical stage!

HIV CDC / WHO stage:

H) Tuberculosis

Acute Tuberculosis ? ☐ Yes ☐ No

I) Treatment

(without antiretroviral treatment)

Treatment indicated ? ☐ Yes ☐ No

Admission to hospital ? ☐ Yes ☐ No

Diagnosis 1: Medication / Consequences

Diagnosis 2: Medication / Consequences

Diagnosis 3: Medication / Consequences

TB treatment ? ☐ Yes ☐ No

If yes, specify: ☐ Ethambutol ☐ Rifampicine ☐ Pyrazinamide

☐ Isoniacide ☐ Streptomycine ☐ Rifabutine

Date of initiation: dd/mm/yy

J) OI prophylaxis

OI prophylaxis indicated ? ☐ Yes ☐ No

If yes, which drug(s) ? ☐ Cotrimoxazole Dosage:

☐ Other drug Name + Dosage other drug:

K) Antiretroviral Treatment

Old drug regimen continued ?

☐ Yes If yes, do not answer the following questions ! Continue with "date new visit".

☐ No If no, continue !

Drug regimen interrupted ?

☐ No

☐ Yes If yes, indicate reason:

☐ TB treatment ☐ Drug toxicity ☐ Other

Specify other:

Restart of old drug regimen after interruption?

☐ Yes If yes, do not continue ! Indicate date of restart: Date of restart: dd/mm/yy

☐ No If no, answer following questions !

Change of drug regimen required ?

☐ No

☐ Yes If yes, indicate reason:

☐ Traetment failure ? If yes, do not continue ! Allocate new appointment to the patient in 2 weeks. Continue in 2 weeks with the form "treatment failure".

New appointment in 2 weeks: dd/mm/yy

If no "treatment failure", continue:

☐ TB treatment

☐ Drug toxicity (maximal viral load suppression)

☐ Insufficient drug adherence

☐ Other reason Specify reason :

ART Programme Uganda | Follow-up visit

Patient registration number: ☐ Date: ☐ dd/mm/yy

New antiretroviral regimen: ☐ Start today ? ☐ Start later ? Date of initiation : ☐

Nucleosidale reverse transcriptase inhibitors (NRTI):

☐ Zidovudine (AZT) 2 x 300 mg	If other dosage, indicate:	☐
☐ Didanosine (DDI) 1 x 400 mg	If other dosage, indicate:	☐
☐ Stavudine (d4T) 2 x 40 mg	If other dosage, indicate:	☐
☐ Lamivudine (3TC) 1 x 300 mg	If other dosage, indicate:	☐
☐ Abacavir (ABC) 2 x 300 mg	If other dosage, indicate:	☐
☐ Combivir (AZT + 3TC)		
☐ Trizivir (AZT + 3TC + ABC)		

Non-nucleosidale reverse transcriptase inhibitors (NNRTI):

Nevirapine (NVP) 2 x 200 mg	If other dosage, indicate:	☐
Efavirenz (EVF) 1 x 600 mg	If other dosage, indicate:	☐

Protease inhibitors (PI):

☐ Indinavir (IDV) 3 x 800 mg	If other dosage, indicate:	☐
☐ Nelfinavir (NFV) 2 x 1250 mg	If other dosage, indicate:	☐
☐ Amprenavir (APV) 2 x 1200 mg	If other dosage, indicate:	☐
☐ Saquinavir sgc (SQV/sgc) 2 x 1600 mg	If other dosage, indicate:	☐
☐ Lopinavir/Ritonavir (LPVr) 2 x 400/100 mg	If other dosage, indicate:	☐

Protease inhibitor-combinations:

☐ Ritonavir / Saquinavir hgc (RTV/SQV-hgc) 2 x 100/1000 mg	If other dosage, indicate:	☐
☐ Ritonavir / Indinavir (RTV/IDV) 2 x 100/800 mg	If other dosage, indicate:	☐
☐ Ritonavir / Amprenavir (RTV/APV) 2 x 100/600 mg	If other dosage, indicate:	☐

Other drug 1:	☐	Dose drug 1:	☐
Other drug 2 :	☐	Dose drug 2:	☐

How many drugs were changed? ☐ 1 drug ☐ 2 drugs ☐ 3 drugs ☐ 4 drugs ☐ 5 drugs

Current form complete?	☐ Yes	☐ No
Summary forms complete?	☐ Yes	☐ No

Date new visit: ☐ *Signature:* ☐

ART Programme Uganda — Treatment failure

Patient registration number _____ Date _____ dd/mm/yy

PMTCT number _____ - page 1 -

Name: _____ Surname: _____

A) Viral load and CD4 count

Please indicate last CD4 count and viral load:

Last viral load:	c / ml	Date last viral load:	dd/mm/yy
Last CD4 count / absolute number:	/µl	Last CD4 count percentage:	%
		Date last CD4 count:	dd/mm/yy

To confirm treatment failure, CD4 count and viral load have to be determined again, at least 2 weeks later ! Please take blood as described and indicate actual VL and CD4 count:

Current viral load:	c / ml	Date current viral load:	dd/mm/yy
Current CD4 count / absolute number:	/µl	Current CD4 count / percentage:	%
		Date current CD4 count:	dd/mm/yy

B) Confirmation of treatment failure

Treatment failure confirmed ?

☐ Yes If yes, coninue !

☐ No If not, return to last follow up form and continue old drug regimen !

C) Type of treatment failure

Please, indicate type of current treatment failure (several answers possible).

☐ Failure to suppress VL initially:

☐ After 2 month of therapy ☐ After 6 month of therapy

☐ Re-increasing VL after initial maximal suppression

☐ Consistent CD4 cell decline

☐ Clinical deterioration

ART Programme Uganda

Treatment failure

Patient registration number

Date dd/mm/yy

D) Causes of treatment failure

If possible, indicate probable causes of treatment failure (several answers possible)

☐ Insufficient drug adherence, because of:

- ☐ Drug toxicity / adverse events
- ☐ Complicated intake schedule of drugs
- ☐ High costs of drugs
- ☐ Other

Specify other:

☐ Drug interactions

Suspected drug 1:

Suspected drug 2:

Suspected drug 3:

☐ Drug resistance

☐ Other reason

Specify reason:

E) Resitance testing

Resistance testing indicated ?

☐ Yes

☐ No1

If yes, continue directly to the form "Resistance testing" !

Summary forms completed ? ☐ Yes ☐ No

Signature:

ART Programme Uganda | Resistance testing

Patient registration number | Date dd/mm/yy

PMTCT number - page 1 -

Name: Surname:

A) Indication

Please, explain indication for resistance testing (only one answer possible):

- ☐ Insufficient VL suppression after initiation of ARV therapy
- ☐ Re-increasing VL after initial maximal suppression

B) Standard form for laborytory

Please, complete "Standard form for laboratory in Germany" and take blood samples.

C) New appointment

Allocate new appointment to the patient, when laboratory results will be available (5 weeks later) !

New date (5 weeks later): dd/mm/yy

D) Results

Date (results): dd/mm/yy

Codon mutations RT gene:

Codon mutations protease gene:

Nucleosidale reverse transcriptase inhibitors (NRTI) :

☐ Zidovudine (AZT)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Lamivudine (3TC)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Didanosine (ddI)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Stavudine (d4T)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Zalcitabine (ddC)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Abacavir (ABC)	Level of resistance:	☐ High	☐ Possible	☐ None

☐ Multi NRTI (a)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Multi NRTI (b)	Level of resistance:	☐ High	☐ Possible	☐ None

Non-Nucleosidale reverse transcriptase inhibitors (NNRTI) :

☐ Nevirapine (NVP)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Efavirenz (EFV)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Delavirdine (DLV)	Level of resistance:	☐ High	☐ Possible	☐ None

Protease inhibitors (PI) :

☐ Saquinavir (SQV)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Ritonavir (RTV)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Indinavir (IDV)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Nelfinavir (NFV)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Amprenavir (APV)	Level of resistance:	☐ High	☐ Possible	☐ None
☐ Lopinavir/r (LPVr)	Level of resistance:	☐ High	☐ Possible	☐ None

ART Programme Uganda | Resistance testing

Patient registration number _____ Date _____ dd/mm/yy

E) New antiretroviral regimen

Date of initiation: _____ dd/mm/yy

Nucleosidale reverse transcriptase inhibitors (NRTI):

- ☐ Zidovudine (AZT) 2 x 300 mg — If other dosage, indicate: _____
- ☐ Didanosine (DDI) 1 x 400 mg — If other dosage, indicate: _____
- ☐ Stavudine (d4T) 2 x 40 mg — If other dosage, indicate: _____
- ☐ Lamivudine (3TC) 1 x 300 mg — If other dosage, indicate: _____
- ☐ Abacavir (ABC) 2 x 300 mg — If other dosage, indicate: _____
- ☐ Combivir (AZT + 3TC)
- ☐ Trizivir (AZT + 3TC + ABC)

Non-nucleosidale reverse transcriptase inhibitors (NNRTI):

- ☐ Nevirapine (NVP) 2 x 200 mg — If other dosage, indicate: _____
- ☐ Efavirenz (EVF) 1 x 600 mg — If other dosage, indicate: _____

Protease inhibitors (PI):

- ☐ Indinavir (IDV) 3 x 800 mg — If other dosage, indicate: _____
- ☐ Nelfinavir (NFV) 2 x 1250 mg — If other dosage, indicate: _____
- ☐ Amprenavir (APV) 2 x 1200 mg — If other dosage, indicate: _____
- ☐ Saquinavir sgc (SQV/sgc) 2 x 1600 mg — If other dosage, indicate: _____
- ☐ Lopinavir/Ritonavir (LPVr) 2 x 400/100 mg — If other dosage, indicate: _____

Protease inhibitor-combinations:

- ☐ Ritonavir / Saquinavir hgc (RTV/SQV-hgc) 2 x 100/1000 mg — If other dosage, indicate: _____
- ☐ Ritonavir / Indinavir (RTV/IDV) 2 x 100/800 mg — If other dosage, indicate: _____
- ☐ Ritonavir / Amprenavir (RTV/APV) 2 x 100/600 mg — If other dosage, indicate: _____

Other drug 1: _____ Dose drug 1: _____

Other drug 2 : _____ Dose drug 2: _____

Summary forms complete? ☐ Yes ☐ No

Date new visit (in 2 weeks): _____ *Signature:* _____

ART Programme Uganda

Drop out Form

Patient registration number:

PMTCT number:

Date of drop out: dd/mm/yy

Name: Surname:

Reasons for drop out:

(several answers possible)

- ☐ Death
- ☐ Severe illness — Specify illness:
- ☐ Side effects — Specify side effects:
- ☐ Lack of money
- ☐ Move to another place
- ☐ Refuse to folllow up
- ☐ Other reasons — Specify reasons:

Additional comments: