

Screeni	ng Lo	g ID I	Numl	ber	A
	-	П			Bronchiolitis
Site ID #	Scre	ening	Log ID	#	Letteria
					Unicha

А

A. Inclusion/Exclusion Criteria

Inclusion Criteria	Yes	NO	
2. First time wheezing or respiratory distress			If NO, STOP HERE
3. Age 60 days or greater, but less than 12 months			If NO, STOP HERE
4. English or Spanish speaking			If NO, STOP HERE

If any inclusion criteria are NO, stop here. Discontinue patient screening, patient is not eligible.

Exclusion Criteria	Yes	No	_
5. PMH bronchitis, bronchiolitis, wheezing, asthma, RAD, or use of albuterol > 7d prior to today			If YES, STOP HERE
6. Prior adverse reaction to dexamethasone			If YES, STOP HERE
7. Any steroid medication taken in the past 14 days			If YES, STOP HERE
8. Known Heart Disease			If YES, STOP HERE
9. Known Lung Disease			If YES, STOP HERE
10. Premature Birth (< 36 weeks gestational age)			If YES, STOP HERE
11. Immune Suppression or Deficiency			If YES, STOP HERE
12. Chicken Pox (active or exposed within 14 days)			If YES, STOP HERE

If any exclusion criteria are YES, stop here. Discontinue patient screening, patient is not eligible.

Qualifying Vital Signs Time (24 hou			
Hour Minute	le		
Temperature	Heart Rate	Respiratory Rate	Room Air Saturation (O2Sat)
Not Available	Not Available	Not Availab	le Not Available
Qualifying RDAI Time (24 hour clock,	Midnight 00:00) RDAI:		
Hour Minute Not Availab	le 🔄 🗆 l	Not Available	
Assess Severity			
13. If mild (RDAI < 6) check this	box 🔲 and stop here .		Patient is not eligible
Enrollment in Study			
14. If parent(s)/guardian(s) dec	line enrollment, check this	box and stop here.	Patient is not eligible
After obtaining parent/guardiar	signature on consent form,	assign Patient Study II	D Number and please proceed.
15. If child needs ET tube or IC	U admission before study	^r med can be given , ch	eck this box and stop here . Patient is not eligible
If all the above criteria are met, B. Patient Information, C. Bron			ollowing forms:
Date of Visit	Date of Birth		RA or PI Initials
Month Day Year Patient Study ID Number	Month Day Vial Number	Year	
		\Box	
Site ID # Study ID #			For Randomization Use
	FOR PUBL	IC RELEAS	SE Version 4 9/20/05

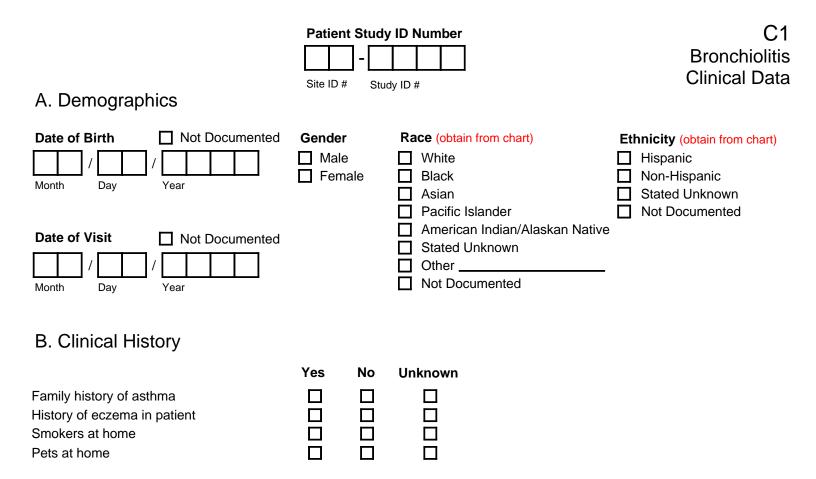
Patient Study ID Number

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		-				
Site ID #		Study ID #				
		0.000 .00				

B Bronchiolitis Patient Information

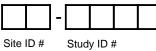
1. Patient Information

First Name:	Last Name:
Date of Visit Image: Month day day	Medical Record Number
2. Contact Information	
Parent/Guardian:	Relationship to Patient:
Parent/Guardian Phone Number	Cell Phone Number
Beeper/Pager Number	Other Phone Number
Other Contact :	Relationship to Patient:
Other Contact Phone Number	Other Contact Phone Number
Contact Notes (For RA follow-up use only)	



	Patient Stud	ly ID Number udy ID #]			C2 Bronchiolitis Clinical Data
C. Drug Administration Time Consent Signed (24 hour clock, Midr Hour Minute	night 00:00)	Vial Numb	er Place Via	al Sticke	er Here	
Time Drug Given (24 hour clock, Midnight 0 Hour Minute	D:00)	Weight: Dose:] • []] 1 ml /]	kg kg, rounded off; n	nax 12 ml
Did the child vomit within 20 minutes of	taking medication?		→ If YES , c Available	omplete	AE form	☐ No ☐ Unknown
D. Treatment						
Aerosol Treatments		Number of Treatments	Continu	uous		
Albuterol / Levalbuterol aerosol						
Epinephrine aerosol						
If both, which was used FIRST?						
Albuterol aerosolEpinephrine aerosol			Vaa	No		
Supplemental oxygen given any time du Virology done Chest x-ray done	ıring 4 hour observ		Yes □ □		Unknown	

Patient Study ID Number



E. Observation Examinations

One Hour After Time Drug First Given
1 hour Vital Signs Time (24 hour clock, Midnight 00:00)
: Not Available
Hour Minute
Temperature Heart Rate Respiratory Rate Room Air Saturation (O2Sat)
. Not Available Not Available Not Available Not Available % Not Available
1 hour RDAI Time (24 hour clock, Midnight 00:00) RDAI:
Image: Not Available Image: Not Available
Hour Minute
Four Hours After Time Drug First Given
4 hour Vital Signs Time (24 hour clock, Midnight 00:00)
Not Available
Hour Minute
Temperature Heart Rate Respiratory Rate Room Air Saturation (O2Sat)
Not Available
4 hour RDAI Time (24 hour clock, Midnight 00:00) RDAI:
Not Available
Hour Minute
F. Disposition
Time of Decision to Admit or Discharge (24 hour clock, Midnight 00:00)
Not Available
Disposition (check one)
Home Admit: general inpatient ICU Transferred to OR Admit: short-stay (< 24 hour)/observation unit
Other (Describe):
Did patient complete ED observation as intended?
If NO, give reason (check first box that applies; check only one box):
ET intubation during observation* Parent withdrew from study**
□ ICU admission during observation* □ Left without completing treatment**
Early admission (before 4 hours)**
Early discharge (before 4 hours)**
Other (specify):
*Complete a Serious Adverse Event Form
**Complete protocol deviation form

	Patient Study	y ID Number	D
			Bronchiolitis
	Site ID # Stu	idy ID #	Follow-up
A. Chart Follow-up			
Viral Result (check one)	Chest X	-ray (check one)	
Not Done			
Positive (check all that apply) ↓ RSV	_	nal (unremarkable) sistent with bronchiolitis (words	such as air tranning
 Influenza Parainfluenza 	nonsp	pecific changes, hyperinflation, pe ening, patchy infiltrates, atelectasi	erihilar infiltrates, peribronchial
Other Virus		r or segmental infiltrate specif	ically mentioning possible
 Negative Report not available 	☐ Othe	erial pneumonia r	
		ort not available	
B. Parent/Guardian Follow-up			
bate Parent/Guardian Follow-up Completed			
Month Day Year	Patie	ched, but declined interview ent considered unreachable / lo all reasonable attempts over 3 to 4 da	
Initial Admission	Signatur	re and date of RA completing f	ollow-up
1. Patient admitted during initial study ED visit?] Yes → Got	ro question 2 🔲 No —	→ Skip to question 3
2. If Admitted Initially, what day did you	ur child ao home	?	
Date Discharged Still Admitted (If checked Image: A strain of the strain of	0		ED , answer question 3 below
3. If Not Admitted, was your child later a	admitted to a hos	spital? 🛛 Yes 🛛	No
If YES, what day? (complete SAE form) Date Admitted		If NO, did your child need visit to the doctor or emergy you went home from the find	gency department since
		Yes> Please record	date below (complete AE form)
Month Day Year		Date of Visit	Not Documented
Hospital Name if not same institution:			
If YES, what was the diagnosis or problem at	that time?	Month Day If YES, what was the diagn	y Year osis or problem at that time?
4. At anytime after leaving the ED was your child medicine? (decadron, orapred, pediapred, prel		eroid 🗌 Yes 🔲	No 🔲 Unknown
5. I'm going to read you a statement and ask you	to respond: "The s	study medicine was helpful to	my child." <i>Do you:</i> (check one)
Strongly Disagree Somewha	at Disagree	Somewhat Agree	Strongly Agree
If not answered: I Not Sure Refuse/Unable to answer			Version 4 9/20/05

Patient Study ID Number



E1 Adverse Event Reporting Form

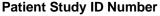
Non-Serious Adverse Event Reporting Form

Adverse Event (AE): Any unfavorable and unintended sign or event, symptom, or disease temporally associated with the use of an investigational drug product, whether or not considered related to the investigational drug product. Complete one form for each adverse event. See AE reporting instructions for more details.

If event is fatal, life-threatening, disabling, requires hospitalization or prolongs hospitalization you *do not* need to fill out this form. Please complete the *Serious Adverse Event Reporting Form* instead.

1. Description of Event	
Provide diagnosis or sign/symptom when possible	
Date of Event Not Documented Time of Event (24 hour clock, midnight is 00:00) Image: Month / Image: Month / Image: Month Month Day Year	
2. Was the event related to the study drug? (check one)	For PC or PI use only.
 Unrelated (no reasonable temporal relationship) Possibly related Possibly related if any one of these: has a reasonable temporal relationship to intervention could not readily have been produced by the research participant's clinical state could not readily have been due to environment or other interventions follows a known pattern of response to intervention 	
Probably related	
 Probably related if 3 of these: 1. has a reasonable temporal relationship to intervention 2. could not readily have been produced by the clinical state, environment, or other interventions 3. follows a known pattern of response to intervention 4. disappears or decreases with reduction in dose or cessation of intervention 	
Definitely related (highly unlikely in this study due to single dose of study drug)	
Definitely related if <i>all 4</i> of these: 1. has a reasonable temporal relationship to intervention 2. could not readily have been produced by the clinical state or environmental or other interventions, 3. follows a known pattern of response to intervention, 4. disappears or decreases with reduction in dose or cessation of intervention and recurs with re-exposure.	
3. Grade severity of the event.	
 Mild (transient, no special treatment or intervention) Moderate (alleviated with simple therapeutic treatment) Severe (requires therapeutic intervention, but no hospitalization) 	
4. What was the outcome?	
 Resolved; patient discharged to home Improving; patient discharged to home No change; patient discharged to home No change; patient discharged to home Ongoing 	bronchiolitis

Participating Clinician or Principal Investigator Signature:





Serious Adverse Event Reporting Form

Serious Adverse Event (SAE): If event is fatal, life-threatening, is disabling or requires hospitalization or prolongs hospitalization then complete SAE form and fax to study coordinator. Complete one form for each Serious Adverse Event and fax to the Study Coordinator at (801) 585-3243 within 7 days. See AE reporting instructions for more details.

If event is **NOT** fatal, life-threatening, disabling, requires hospitalization or prolongs hospitalization you **do not** need to fill out this form. Please complete the **Non-Serious Adverse Event Reporting Form** instead.

Important Note: <u>For this study</u>, initial hospitalization for Bronchiolitis will be reported in aggregate and does not require completion of this form. If the admission is for an event or diagnosis other than Bronchiolitis, you must complete this form. Please note that your local IRB may have additional reporting requirements.

1. Description of Event (Provide diagnosis or sign/symptom when possible)

Date of Event Not Documented Time of Event (24 hour clock, midnight is 00:00) Discharge Date Not Documented Month / / / / Month Day / Year Hour Minute
2. Check if SAE is one of the following: For PC or PI to complete. PI must review.
Significant GI Bleeding Excessive agitated behavior Significant hypertension
3. Was the Serious Adverse Event unexpected?
(Unexpected: an SAE that is not consistent with the risk information described in the protocol or consent form.)
4. Was the event related to the study drug? (check one)
 Unrelated (no reasonable temporal relationship) Possibly related Possibly related if any one of these: has a reasonable temporal relationship to intervention could not readily have been produced by the research participant's clinical state could not readily have been due to environment or other interventions follows a known pattern of response to intervention
Probably related
Probably related if 3 of these: 1. has a reasonable temporal relationship to intervention 2. could not readily have been produced by the clinical state, environment, or other interventions 3. follows a known pattern of response to intervention 4. disappears or decreases with reduction in dose or cessation of intervention
Definitely related (highly unlikely in this study due to single dose of study drug)
 Definitely related if all 4 of these: 1. has a reasonable temporal relationship to intervention 2. could not readily have been produced by the clinical state or environmental or other interventions, 3. follows a known pattern of response to intervention, 4. disappears or decreases with reduction in dose or cessation of intervention and recurs with re-exposure.
5. What was the outcome? (RA may complete)
 Resolved; patient discharged to home Improving; patient discharged to home No change; patient discharged to home Patient admitted to hospital for bronchiolitis Patient admitted to hospital after discharged to home or admitted for specific adverse event (eg. irregular heart rhythm) Worsening; admitted to PICU Deceased Unknown Ongoing
I certify that I have reviewed this event Principal Investigator Signature

In all cases, fax to Study Coordinator: (801) 585-3243 within 72 hrs.

*IF unexpected SAE, fax to Study Coordinator and DSMB Monitor: (916) 734-5333 within 24 hrs.

Summary Changes to Bronchiolitis Case Report Forms

Resulting in Version 4, 9/20/05

Form A. Enrollment: 1) removed statement/signature line for participating clinician to certify that the patient has disease consistent with Bronchiolitis.

Form B. Patient Information: NO CHANGES

Form C. Clinical Data: 1) removed question from C1, section B. Clinical History: Number of days illness present, including today. 2) NO CHANGES to C2 or C3

Form D. Follow-up:1) added signature line and date for research assistant completing follow-up telephone call.

Form E. AE Reporting: 1) NO CHANGES to E1; 2) added note about local IRB reporting requirements for AE/SAE; 3) added discharge date; 4) changed DSMB monitor fax number.